Submitter : Mrs. Margaret Simon **Date:** 04/25/2005

Organization : Santee-Wateree Mental Health Center

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I strongly support the Competitive Acquisition Program for Outpatient Drugs and Biologics. With my position at the Community Mental Health Center level, I also see the benefits for all mental health patients to have this available to the mental health class of medications as well. We have had many difficulties supplying the injectible medications to our patients because of reimbursement issues in acquiring these medications.
The entire class of mental health injectible medications should be included from day one, January 1, 2006.
Thank you for your consideration on this matter.

Submitter : Dr. anthony coscia **Date:** 04/25/2005

Organization : norwalk medical group

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-227-Attach-1.DOC

I have long supported, in letters to Congress, the President, and CMS, the potential for MVI (CAP) to be a rational solution to many of our fiscal issues in the delivery of cancer chemotherapy in the outpatient setting. However, the proposals put forth by CMS for comment have made it abundantly clear that MVI (CAP) is going to be an overwhelming failure. Congress and CMS have taken a functional though defective system and done the impossible - produced a non-functional and more highly defective system.

First of all, and very importantly, the current fallback of MVI plus 6% (a backup for those who don't wish to utilize MVI in 2006) is barely viable in 2005 even with the demonstration project. In 2006, without the demonstration project, it is a financial disaster to most practices and therefore will not represent a realistic option to MVI. If MVI turns out to be a failure, I and most other oncology practices will therefore have no choice but to send our Medicare beneficiaries to other facilities for their treatments, if such facilities exist in sufficient number to handle this patient volume. And I am convinced these facilities (most of which will be hospital based) will be a lot more costly to the Medicare system and the American taxpayer.

Secondly, MVI as currently proposed, will be an incredibly convoluted system that will put a tremendous administrative burden on my nursing and administrative staff (not to mention the physicians); this will be disruptive to the efficient flow of patient care and indeed detract from patient care as health care professionals try to negotiate the complex bureaucracy of MVI. My office has already be partially overwhelmed by the 2005 changes mandated by the MMA of 2003, and the 2006 changes are truly monumental and unworkable, especially as all this additional administrative work will be totally uncompensated. You must realize that I cannot exist as a business if you expect me to do your work for free.

One could go on for hours - I have already spent days writing to everyone since 2003 with little to nothing to show for it in terms of Congress, the President or CMS understanding the complexities of providing oncology therapy in the outpatient setting. You have already been told of the innumerable problems with the MVI proposal you have put forth. Additional issues that may not have been mentioned by others include such simple things as

1. how does the system handle a change in dosage of a drug that is (and must be) made on the day of treatment?? If I use 2 vials of a medication instead of the original planned 3 vials (because it would not be safe to give the 3 vials), how do I handle the 3rd vial that is left over??
2. also, a big issue is vendor performance. If I am locked in to a vendor for a year, competition amongst vendors has essentially been eliminated; competition is one of the strongest factors in ensuring maximum quality from vendors in 2005 as we can instantly leave a vendor if we are dissatisfied with their performance. Under MVI I could not leave an unsatisfactory vendor except after a presumably long period of time during which I would have to prove to CMS that the vendor was not performing up to a reasonable standard.
3. limited formularies are totally unacceptable as they will restrict my ability to practice medicine as I deem the best for each individual patient; as the treating physician, I consider my knowledge of cancer treatment superior to that of any non-physician. Each vendor must make available every chemotherapy agent that is available commercially.

I fully realize the deficiencies of our system prior to January of 2004. However, the modifications put in place in 2004 and 2005, and most importantly planned for 2006, have in reality done little to make a better system. The decisions made by Congress in the MMA clearly reflected a lack of even an elementary understanding of the complexities of providing medical oncology services in the office setting. I hope key players come to their senses before January 1, 2006, as I strongly believe the system is in danger of total failure.

Sincerely,

Anthony G. Coscia, MD
203-845-2055 office
203-845-2165 fax

P.S. As this is a commentary on the current MVI/CAP proposal, I did not feel it appropriate to offer alternative suggestions for improving the system. I would be more than happy at any time to discuss my thoughts.

Submitter : Dr. Warren Garrison **Date:** 04/25/2005

Organization : Columbia Area Mental Health Center

Category : Physician

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

All mental health injectible medications should be included from the first day of the CAP initiation in January of 2006.

Claims Processing Overview

Presently in South Carolina, the Medicare reimbursement landscape is improving, but we have been experiencing several months of delayed payment and slowed acquisition for patients due to this reimbursement delay.

Submitter : Dr. Ramesh Gihwala

Date: 04/25/2005

Organization : Pathways Mental Health Center

Category : Physician

Issue Areas/Comments

1-15

Overview of the CAP

I am writing in strong support of the proposed rule recently issued by the Centers for Medicare and Medicaid Services (CMS) that addresses implementation of the Competitive Acquisition Program (CAP). This program has tremendous potential to benefit individuals with severe and persistent mental illnesses for whom injectable medications can help maintain adherence to drug regimens, treatment that is life-saving and essential to successful rehabilitation outcomes. We urge that injectable antipsychotic medications be included in the initial phase of CAP implementation.

Categories of Drugs to be Included under the CAP

From a brief review of the proposed rule, it appears that CMS may view oncology medications as the primary medication category to be included in the initial phase of CAP. CAP also has the potential to bring new psychiatric therapies into wider use and to significantly improve the quality of care for some of the most vulnerable people in our society ? helping to ?achieve the promise? of the New Freedom Initiative for people with psychiatric disabilities. We urge you to include coverage of antipsychotic injectable medications in the drug categories that compose the initial phase of CAP implementation.

Claims Processing Overview

Unfortunately, community mental health centers (CMHCs) and other multi-service community providers, which serve a large number of people with severe mental illnesses that are eligible for both Medicaid and Medicare, face serious obstacles in providing injectable medications. As safety-net providers, CMHCs are very often heavily burdened treatment settings that lack sophisticated information technology and a sufficient level of administrative staffing. For example, to provide the new injectable antipsychotic risperidone to patients, CMHCs must first purchase the medication, and then seek reimbursement from both Medicare (which makes only partial payment for mental health drugs) and Medicaid. Providers then bear the administrative burden of tracking the claims and the financial risk of receiving incomplete payment from one or both payers. This burden has become an impediment to expanding access to this medication to the full range of patients who could benefit from it. In some cases, CMHCs will only provide the medication to patients that are solely Medicaid beneficiaries. When injectable antipsychotics are included in the Medicare CAP program, this substantial impediment will be removed, as providers would have the option to obtain the medications from a drug vendor that will handle reimbursement from Medicare. Helping providers expand access to this medication will bring great benefit to our patients with schizophrenia.

Submitter : Dr. Mark Amdur **Date:** 04/25/2005

Organization : Thresholds Psychiatric Rehabilitation

Category : Physician

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

I am the Medical Director of a large psychiatric rehabilitation agency in Chicago. I am writing to urge inclusion of psychiatric medications. In particular I am writing to urgently request that long-acting injectable anti-psychotic medications be available on a "barrier-free" basis to the chronically mentally ill. The current landscape means that medicare-only patients get "standard-of-care" treatment (Risperdal Consta by Janssen) only through the charity of Janssen. Dual-eligible patients are effectively precluded from obtaining the drug at all.

Neither our agency nor our consulting psychiatrists are in a position to purchase drugs "up front" and then bill. Billing for pharmaceuticals has never been an activity of our agency or our physicians. We simply do not have the "back-room" staff or expertise to bill for physician-administered medications. I believe that we are typical of most community mental health centers.

There currently exists monumental disincentives for medicare-only and dual-eligible patients in particular to receive "standard of care" treatment for chronic psychotic mental illness. Provisions to allow pharmacies to directly bill for physician-administerd anti-psychotic medication are desperately needed.

In the interests of brevity, I will not discuss why long-acting injectable medications are of critical importance in the out-patient treatment of persons with schizophrenia and other chronic psychotic conditions.

Also in the interests of brevity, I will omit a discussion as to why Risperdal Consta represents the "standard of care" treatment that is essentially being denied under current regulations.

I would be glad to defend these positions in detail if the agency lacks knoweledgeable "in house" psychiatric consultation.

Am I simply a "shill" for Janssen? Absolutely not. I have no love for the pharmaceutical industry. I have a published letter highly critical of Janssen. Risperdal Consta is a long-awaited improvement over fluphenazine and haldol injections, but Risperdal Consta is far from perfect.

Unless there is "barrier-free" access to obtain the drug, it will go unused. Janssen and other companies will come to feel that there is no market for long-acting injectable anti-psychotics. We will never see a drug with more than a two week duration of action. We will never see a drug that is free of hormonal side effects. We will never see a drug that is free of neurological side effects. We will never see a drug that enhances cognitive performance.

I write this comment not on behalf of Janssen, but on behalf of the important advances that need to be made in the next decade. Unless physician-administered medications are easy to obtain, no market will develope. There will be no incentive to seek and market better drugs.

Yours truly,

Mark A. Amdur MD
Medical Director
Thresholds
3303 S. Halsted, Room 205
Chicago, Illinois 60608
773-523-8745 (voice)
773-523-8746 (fax)
amdurm@sbcglobal.net (email)

Submitter : Mr. Timothy Hensley

Date: 04/25/2005

Organization : Communicare

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I believe the best option is the CAP proposed rule allowing the CMS to select up to five specialty pharmacy provider vendors to offer categories of Part B drugs. This would taken the administrative burden off of Community Mental Health Centers in terms of handling billing aspects of obtaining much needed medications for consumers and allow psychiatrist and nurses to cut back on bureaucratic tasks. This in turn would allow more time for time for direct service with consumers.

thank you for your time,

Tim Hensley RN
Emergency Services Coordinator
Communicare Inc.
Elizabethtown, KY

Submitter : **Dr. richard heppe** **Date: 04/25/2005**

Organization : **Rocky Mountain Urological Society**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

I am the president of the Rocky Mountain Urological Society, the state society for Urology in Colorado. Our organization represents 96 urologists in Colorado as well as areas of Wyoming and Nebraska.

This comment is in regards to the proposed Competitive Acquisition Program (CAP). Your comment period ends 4/26 and the program is set to be instituted 1/1/06.

Several significant problems are apparent with this program on even a cursory review. First, physicians are obligated to participate for a full year if they sign up. This is unacceptable because if a physician has difiiculties with the program he cannot opt out immediately. He and his patients will be stuck with a suboptimal provider for a year. They will have to bear the consequences of a decision made in 05 with absolutely no knowledge what-so-ever of the efficiency of service of the CAP vendor.

Second, the CAP vendor will have the discretion to supply a different drug than the one requested by the physician if the drugs share a HCPCS code. This is arbitrary and is also unacceptable. The physician should be able to make the decision as to what drug to administer to his patient. The drugs vary in qualities and modes of administration and are not interchangeable. To leave the choice of drug up to a third party vendor who has not seen the patient and has no knowledge of medicine is outrageous.

Further, the CAP vendors will not be required to offer every dose available of the various LHRH agonists. The physicians and their patients will be at the mercy of the purchasing agent of the vendor as to what treatment will be available. Again, this is unsatisfactory.

Finally, it appears that CMS feels that there will be less administrative cost for physicians that participate in the CAP program than in the traditional form of drug purchasing. I disagree. In order to utilize the CAP program the physician has to anticipate several days before he will administer the drug so that it may be ordered. At least 30% of doses of LHRH agonists are administered due to a decision made during that visit.

The CAP program will require these patients to return for another visit, placing a burden on the patient and the physician's schedule. Further, the physician's staff will need to spend time reviewing the schedule and ordering medications in anticipation of individual patient visits rather than ordering the medications in bulk.

Although the physician will be relieved of the carrying cost of the medications and will avoid the potential risk of paying more for the medication than the CMS reimbursement, there will clearly be significant costs associated with the CAP program.

In light of these many profound concerns, it is my opinion and the position of the Rocky Mountain Urological Society that the CAP program be phased in gradually and that physicians only be bound to their decision to be in or out of the program for a 3 month period.

I would be happy to correspond further if any clarification is desired.

Respectfully Submitted,

Dr. Richard Heppe
President, Rocky Mountain Urological Society
4/24/05

Submitter : Mrs. Mary Ellen Artioli

Organization : Mrs. Mary Ellen Artioli

Category : Individual

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-233-Attach-1.DOC

April 21, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8010
Baltimore, MD 21244-8010

RE: CMS-1325-P

To Whom It May Concern:

I am writing to express my concern over the Medicare Program Competitive Acquisition of Outpatient Drugs and Biologicals under Part B.

"Statutory Requirements Concerning Claims Processing"
"Claims Processing Overview"
The offer to streamline this process and allow physicians to save time and paperwork will actually create paperwork and require more staff time. An example of this is providing the vendor with all of the necessary information to bill the patient. Keeping a separate electronic or paper inventory of medications would also create a significant increase in staff time. I am concerned about the patient that after having laboratory work done now needs an adjustment of the dosage of medication. As outlined in case of emergencies, the physicians own stock of medication can be used and then replaced by the vendor. Again, this is an additional recordkeeping burden and will increase costs to the community cancer center. The cancer clinic will also have to accept whatever replacement medication is given which may not be the same product the physician would choose to give.

ASP calculation should not include prompt pay discounts. Paying bills ahead of the due date to obtain an early pay discount is an opportunity for a company to reap the benefit of their sound business practices. Volume discounts are another aspect that should not be factored into this calculation. Hospitals, and especially hospital groups, make substantially larger purchases than the local community cancer center and as such, they receive volume discounts that the small practice will never be able to take advantage of. If these types of discounts are allowed in the calculation of ASP, it has and will unfairly skew ASP to the point where reimbursement will be less than the cost.

Community cancer clinics are such a vital part of this country and are often patients' only option for cancer treatment close to their home. I am concerned that more and more clinics will opt out of the Medicare program because they can not afford to stay in it;

forcing more patients to go to the hospitals which will ultimately cost the Medicare program more.

Thank you for allowing me the opportunity to comment on this program.

Sincerely,

Mary Ellen Artioli

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter : Ms. Sharon Bromley

Date: 04/25/2005

Organization : Summit Cancer Care, P.C.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

Submitter : **Miss. Cheryl Crowe** **Date: 04/25/2005**

Organization : **Miss. Cheryl Crowe**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-235-Attach-1.DOC

April 20, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

Attn: CMS1325-P

To Whom It May Concern:

"Statutory Requirements concerning Claims Processing"
"Claims Processing Overview"
I am writing this because I am highly concerned about effects that the proposed Competitive Acquisition Program (CAP) would have on my community. As you are aware, oncology and the treatment of cancer is unlike many other specialties in the medical arena. In order to provide the drugs necessary to treat cancer, there is the need for professionals to deliver these life saving drugs in a safe manner, including nursing and laboratory staff. By implementing the CAP rule you could be forcing community based oncology centers to close their doors, thereby leaving no option for cancer patients other than being admitted to hospitals for treatment. This could not only jeopardize patient care, convenience and quality of life, but the expense would be much more because Medicare would be paying higher hospital costs for the same treatment.

Under this rule, vendors would only be required to supply one manufacturer's version of a drug in the case of multiple-source drugs and the physician would be forced to use the drug of the vendor's choice. This would be taking away from our highly knowledgeable and qualified physicians' right to choose which drug is the most effective for a specific patient. Medical decision making would be taken out of the hands of the physician and would be at the sole discretion of the vendor. According to this rule, a physician would be able to order an entire regimen for a specific patient at one time; however the vendor could divide the shipment into "appropriately spaced shipments". This would provide a dangerous scenario for the drug not being available at a time that it may be needed due to unseen clinical changes in a patient's condition. Physicians would be required to treat all patients the same and socialized medicine will be brought to the forefront.

It seems to me that the Competitive Acquisition Program (CAP) Rule is more about the dollar than quality of care for the general population. Please consider my comments and take into consideration a better way of price controlling the pharmaceutical companies other than compromising patient care in this manner. I do not recommend use of the Competitive Acquisition Program.

Sincerely,

Cheryl Crowe

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter : Ms. helen shock **Date:** 04/25/2005

Organization : Dr Carol Rapson

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am the business manager for an oncologist. There are many problems w/ this program. #1 is inventory control, this is going to be a another fulltime position to try & keep track of this. #2 pt inconvenience.
#3 locked into the program for 1 yr. #4 What do you do w/ inventory if there is a cancellation. Pt is worse and chemo cancelled or totally changed. #5 add on injections such as Neulasta & Aranesp, keeping track of our inventory vs. CAP inventory. #6 I heard something about the vendors having their own formularies which are driven by price not what the physician ordered. #7 Our pts will have to deal w/ an outside vendor regarding payment for their drugs. #8 Will our patients have to deal with Vendor & their insurance when there are denials. How much will our office have to be involved in the process of getting bills paid. Who will have to deal with the appeals process. Our patients have enough to worry about besides some strangers demanding money from them. #9 How much extra work on our part to supply information to the vendors? If their ins changes, we fax information and it is not captured properly. #10 Quality control & lack of vendor responsibility for drugs delivered and what is their service going to be like.
In summary, I see this program creating a nightmare re: inventory tracking, billing, and patient's having to deal with the government / vendor to have their bills paid. There will be no advocate to fight to get their bills paid properly. I believe this would put a burden on our staff possibly adding on another employee just to do all of the extra work.

Submitter : **Miss. Angela Brinnegar** **Date: 04/25/2005**

Organization : **Coastal Cancer Center**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-237-Attach-1.DOC

04/22/05

Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8010
Baltimore, MD 21244-8010

Attention: CMS-1325-P

To Whom It May Concern:

My name is Angie Brinegar. I am an oncology certified registered nurse from South Carolina. Currently I practice in the community cancer center setting. This morning I am taking time to write you a letter to voice my extreme concern over the proposed CAP (competitive acquisition program) which is due to begin on January 1, 2006.

I must admit that when the first part of the Medicare Modernization Act came to fruition this past January, it was quite overwhelming! But with a lot of hard work, planning, re-education of staff and hours of overtime, our staff has been able to make the changeover so that patient care has not been compromised.

Unfortunately, after reading the recent Medicare fact sheet on CAP, I am very concerned that this will not be the case in January 2006. I am extremely distressed over what this is going to mean to patients, oncology nurses, the community cancer center and even to the future of oncology care for generations to come.

Part of my job as a clinician in our practice requires me to oversee the inventory of drugs for our patients. This is a very tedious process at times but at least I have control over the inventory and know that I have drugs available for our patients at their time of treatment. Typically drugs are supplied to us by our vendor or vendors, and they are inventoried daily. This includes returning expired drugs, ordering new drugs that come to market and making sure daily that there is enough drug in inventory as need arises. I assure you this is a very big responsibility.

"General Overview of CAP"
The competitive acquisition program proposed rule (CMS-1325-P) is going to create bigger problems for us than you could ever imagine. I believe it is going to be a logistical nightmare firstly for physicians and their staff with greater workload and less reimbursement, but ultimately for the patient. The cancer center will have to hire extra staff just to oversee and expedite individual drugs for each patient. It is going to require two to three fold the work for each patient and for several days we will still not have what we need to treat the patient. Let me give you a hypothetical example:

Mr. John Smith is a 67 year old patient who was recently diagnosed with small cell lung cancer. He had a complete lobectomy but was found to have metastatic disease to the bone. The physician has seen him and determined that the appropriate treatment will be

the six cycles of Carboplatin and VP-16. These drugs are given 3 days in a row every 21 days. Before I can administer treatment to Mr. Smith, the following things have to be done just so that I can get his drugs. First the physician would have to order the drugs from the vendor. The vendor would have to be advised of dosage, frequency, anticipated date of administration, information about the patient's secondary insurance and additional information such as birth, allergies, height, weight, ICD-9 codes, etc. How is this information to be sent to the vendor and what is is the turn around time for us to receive the order? This will be burdensome to the practice.

Secondly, once the vendor receives the order and processes everything (which will take time), the vendor will send the drugs for Mr. Smith to me with a prescription number which will have to be rechecked against the order to insure that the patient gets the right drug, right dose, right route. It is also my understanding that since the patient will be getting a couplet of drugs, I may receive the Carboplatin on one day and the VP-16 two days later. Should there be a delay, patient's treatment time is also further delayed.

Thirdly, once I finally get the appropriate drugs for Mr. Smith I must then inventory them either electronically or via paper inventory.

Finally Mr. Smith who has small cell lung cancer (a very rapidly growing cancer) gets his treatment. On that day of treatment I must submit the claim to the local carrier and include the drug administration codes and the prescription number supplied by the vendor for the drugs administered.

The local carrier would then adjudicate the claim as usual and would determine whether it was a Medicare-covered service, applying local coverage determinations as applicable. If the service was covered, the local carrier would notify the carrier that handles vendor drug claims of the prescription number involved, at which time the drug carrier would pay the vendor and the vendor would be permitted to bill the patient, or the patient's secondary insurer, for the coinsurance.

Mr. Smith finally got his first cycle of chemotherapy, but on day 8 following treatment he comes in and is neutropenic. Normally, we would give the patient an injection of Neupogen, but will not be able to under the CAP system. The above process will have to be repeated and I fear that by the time we receive the drugs and have the patient come back to the office, he will have developed febrile neutropenia, a potentially fatal condition, and will need to be hospitalized.

I do realize that the CAP is an option for physicians, however, that does not take away the great concern that I have for the delivery of quality, expedient cancer care. The other concern is the enormous amount of clerical work that will be required in this program. I believe it will in the end cost more money and create such a burden on those in the clinical arena that many out patient practices will be forced to close.

Although I have been an oncology nurse for only seven years, the changes have been enormous. What we attempted to do in the last decade, i.e., take patients out of the expensive hospital setting and treat in the outpatient setting is eroding.

I understand that there had to be changes made, but it seems changes such as the CAP will not help cancer patients but will provide obstacles to care.

Oncology nurses such as myself are the ones who see the difference oncology care makes for our patients. Please do not add to this burden. As a provider of cancer care and speaking as one for whom this change will directly impact, I respectfully ask you to re-examine this system and come up with a better answer.

Sincerely,

Angie Brinegar, RN BSN OCN
Clinical Educator
Coastal Cancer Center

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter : Dr. Gordon Downey **Date:** 04/25/2005

Organization : Gynecologic Oncology of West Michigan

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I have very significant concerns about the CAP program. As a subspecialist in gynecologic oncology, I have seen first hand, via a member of our Society, what can happen with an unethical pharmacist. Chemotherapy drugs were delivered with labels that were fradulent. This resulted in signicicant harm to patients.
I am also concerned about what would appear to be a substantial administrative burden to keep each patient's individual "orders, ordered drug, received drug", etc. separate from any other patient's ordered drug, etc. We currently maintain inventory sufficient to cover the patients we know we will be seeing that week and sufficient alternative agents to be able to switch the chemotherapeutic drug if, upon examination, the patient has progressive disease or is not responding. How would we be able to accomplish this under the CAP program?
Our patients sometimes drive as much as 2 1/2 hours to get to us. We give them chemotherapy on the same day that we see them. If we cannot order the drug until we have seen the patient and determined if they should continue treatment, same drug or different drug, or change dosage, then our patients would have to come back for their chemotherapy on a separate day. This would significantly impact our patients and their families.
I would be very cautious about signing up with a program that requires a year's committment - when I have concerns about the ability to work within the requirements of such a program.
Thank you for your willingness to consider these concerns.

Submitter : Mrs. Chris Zimmerer
Organization : Mrs. Chris Zimmerer
Category : Individual
Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1325-P-239-Attach-1.DOC

March 18, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8010
Baltimore, MD 21244-8010

Re: **The Competitive Acquisition Program Proposed Rule** (CMS-1325-P)

Dear Sirs:

As a voter and one of your constituents, I would like to take this opportunity to express to you the deep concerns which I have after carefully reviewing the CAP Proposed Rule (CMS-1325-P).

- *Physicians "obtain the drugs" from a Medicare Approved Vendor – who then bills Medicare for these drugs.* This adds another level of bureaucracy (cost/delay) to an already heavily burdened system. It also severs the relationship and access between Medicare and the physician, yet still leaves the physician responsible for ordering, maintaining, preparing and administering the drug.
- *The vendor, rather than the physician, would bill Medicare for the drugs and would be responsible for collecting any deductibles and coinsurance from the beneficiary.* Again, this adds further bureaucracy and ALSO separates the patient from the physician. Far from being a simple matter, having a third party bill for a service the patient receives at their doctors invariably causes confusion and concern to our patients (CLIA forced this on us with certain lab studies several years ago). The patients don't understand the bills, don't know who this company is, and it causes an endless round of phone calls and confusion because they are hypersensitized to watch for fraud against their Medicare number. Usually this third party makes errors in billing the insurance and the patients call us because they don't know with whom to speak to get it resolved.
- *Physicians would choose a sole source of the selected categories of Part B drugs.* Anyone in medicine, or in any industry, knows that sole source is a risky proposition. Will this mean that if a supplier is out of, or unable to get a needed drug our patients will have to do without?
- *The physician would bill only for services involved in administering the drugs using the "newly created codes that better describe the range of services provided".* Notice it says better *describes*, it doesn't say better *reimburses for.* Please remember, we are not talking about giving someone a pill with a little plastic cup and a sip of water, or a flu shot into the upper arm. These are deadly (yet life-saving) drugs that require handling by highly skilled, highly trained nurses, pharmacists or physicians. Many treatments take several hours of careful monitoring (yet are significantly faster in our office than in a hospital outpatient area). An Oncologist does not have the option of cutting staff quality to reduce costs to what Medicare thinks might be a fair price for administration. We have to remember that we are always the ones face-to-face with the patients, bearing the ultimate responsibility and trust of that patient. We take that quite seriously. The new "better" rates for "better described services" don't go nearly far enough to allow the 24 hours a day, 7 days a week operation of a Community based Oncology Practice. That discrepancy is still, albeit to *a much smaller degree* offset by the small profit on the drugs administered.
- *The physician would order the drugs for specific beneficiaries from an approved vendor. The vendor would then bill Medicare.* If a physician were to elect to do this with Medicare, we would have to maintain completely separate drug inventories for Medicare patients vs. non-Medicare patients. If a drug were not on hand for that Medicare patient, their treatment would have to be delayed, we couldn't use drugs out of "stock" to cover while that patient's supply arrived. All drugs on-hand for Medicare patients would, I assume, be only available for that specific patient:

a concern that other insured patients do not face – again a two-tier program. Also, what would be the quality of these drugs?

- *The proposal further states that no vendor should bid higher than 106% of the weighted ASP drugs in that category.* If there is no intent to significantly reduce the amount Medicare is spending on these drugs (i.e. they pay the provider 106% of ASP if they elect not to participate in CAP) than why add all this complication to the program? It will only increase costs by adding another tier of Medicare providers and diverting what little profit may still exist in the drugs away from the physicians and providers who are actually directly servicing the patient (and who at least deserve some return on their labors for their Medicare patients) and route it into the hands of third party mega companies who are structured solely for the purpose of billing Medicare. I believe that is a roadmap to waste and corruption and there is no way that it can serve the interests of the patient.

I know the ever-increasing cost of providing healthcare in this country is of tremendous concern to CMS, our elected officials, patients and especially to the healthcare providers throughout this country. I realize that solving that challenge may require some radical thinking, some enormous changes and many sacrifices on the part of both patients and providers, both physically and financially. Americans are blessed to be living longer, and to have more options than prior generations, and our doctors feel blessed to have the choices to offer them, and the chance to help them spend many more years with the ones they love. But of course, those choices come with a price.

Medicare has long made a commitment to their beneficiaries that they would not become a two-tiered system with services and benefits that put their recipients at a disadvantage and deny options that are available to other beneficiaries of other programs. But it seems to me that many of the changes instituted in the last few years, and especially the CAP Proposed Rule, would do just that to our Medicare enrollees. Physicians could be forced into turning patients away, or making care decisions that are too greatly influenced by financial worries for themselves and their patient. Many physicians now already refuse to see or treat Medicare patients, a sad state of affairs for a huge segment of the population of the greatest nation in the World.

I sincerely appreciate your time and consideration of my concerns. I only ask that you bear these points in mind and work as hard as you can to shape the Medicare Program into an equitable and workable design for the 21st Century. Please feel free to contact me should you have questions or wish to discuss it further.

Yours most respectfully,

Christine M. Zimmerer
PO Box 1111
Pawleys Is., SC 29585

cc: The Honorable Representative Henry Brown
The Honorable Senator Lindsay Graham
The Honorable Senator Jim DeMint

Submitter : Dr. Lawrence Holt

Date: 04/25/2005

Organization : Coastal Cancer Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-240-Attach-1.DOC

April 12, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

ATTN: CMS1325-P

Dear CMS,

I thank you for the opportunity to comment on the Competitive Acquisition Program. As a practicing medical oncologist, I believe that the proposed Competitive Acquisition Program does not serve a patient's best interest and detracts from quality of care.

This system as designed is extremely cumbersome. It does not allow for flexibility of same day treatment decisions for non-emergent situations. This inflexibility detracts from the overall quality of care by limiting the options for patients with cancer. Specifically, treatment decisions cannot be made in a timely fashion and subsequently require a built-in delay of several days for changes in therapy. This will ultimately lead to long-term delays in care for patients. Furthermore, this system does not allow appropriately for the dosage reductions that are frequent in cancer therapy. Additionally, it is unclear as to who pays for unused chemotherapy that is wasted through no fault of anyone's (e.g.: unexpected death or a natural disaster such as we have with hurricanes in our area).

The billing system is cumbersome. The ordering process is cumbersome. Coverage of indigent care (such as patients with no co-pay insurance) becomes a difficult issue, in so far as who covers the cost of the chemotherapy. The administrative work caused by the system is an unfunded mandate from the government. The payment coverage of denials of claim processes as well as the appeals process is not clear. Furthermore, the "acceptable threshold" for denials of a physician's services is also unclear.

In general, this system is quite cumbersome. It does not allow flexibility of same day treatment decisions for non-emergent patients, and overall detracts from the quality of care by limiting the options of patients with a built-in delay.

I thank you for the opportunity to comment on this proposed program. I do not recommend its implementation. More time needs to be spent to work out the mechanisms so that patients are not penalized.

Sincerely,

Lawrence B. Holt, MD
LBH/pjh

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter : Dr. Ali Garatli

Organization : Dr. Ali Garatli

Category : Physician

Date: 04/25/2005

Issue Areas/Comments

GENERAL

GENERAL

Please include PSYCHIATRIC DRUGS AND A MENTAL HEALTH DRUG CATEGORY!
We need included in PSYCHIATRIC DRUGS IN PHASE I.

Submitter : Dr. Jacqueline Feldman **Date:** 04/25/2005

Organization : UAB Community Psychiatry

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-242-Attach-1.RTF

April 12, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

ATTN: CMS1325-P

Dear CMS,

I thank you for the opportunity to comment on the Competitive Acquisition Program. As a practicing medical oncologist, I believe that the proposed Competitive Acquisition Program does not serve a patient's best interest and detracts from quality of care.

This system as designed is extremely cumbersome. It does not allow for flexibility of same day treatment decisions for non-emergent situations. This inflexibility detracts from the overall quality of care by limiting the options for patients with cancer. Specifically, treatment decisions cannot be made in a timely fashion and subsequently require a built-in delay of several days for changes in therapy. This will ultimately lead to long-term delays in care for patients. Furthermore, this system does not allow appropriately for the dosage reductions that are frequent in cancer therapy. Additionally, it is unclear as to who pays for unused chemotherapy that is wasted through no fault of anyone's (e.g.: unexpected death or a natural disaster such as we have with hurricanes in our area).

The billing system is cumbersome. The ordering process is cumbersome. Coverage of indigent care (such as patients with no co-pay insurance) becomes a difficult issue, in so far as who covers the cost of the chemotherapy. The administrative work caused by the system is an unfunded mandate from the government. The payment coverage of denials of claim processes as well as the appeals process is not clear. Furthermore, the "acceptable threshold" for denials of a physician's services is also unclear.

In general, this system is quite cumbersome. It does not allow flexibility of same day treatment decisions for non-emergent patients, and overall detracts from the quality of care by limiting the options of patients with a built-in delay.

I thank you for the opportunity to comment on this proposed program. I do not recommend its implementation. More time needs to be spent to work out the mechanisms so that patients are not penalized.

Sincerely,

Lawrence B. Holt, MD
LBH/pjh

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

SCHOOL OF
MEDICINE

Department of Psychiatry and Behavioral Neurobiology
Community Psychiatry Program

April 25, 2005

Center for Medicare and Medicaid Services (CMS)

Proposed Rule: Competitive Acquisition Program (CMS-1325-P)

As a psychiatrist and MedicallExecutive Director of the University of Alabama.at Birmingham Community Psychiatry Program, I believe it will be crucial that the long-acting injectable anti-psychotics be included in the Competitive Acquisition Program (CAP). Without the inclusion of the current and soon-to-be approved injectable anti-psychotic medications, the implementation of the Medicare Prescription Benefit will not be as accessible to the persons with serious mental illnesses, resulting in significant harm to these individuals.

The majority of mental health centers in the state of Alabama will not have the capacity to purchase these medications on behalf of their patients and file for reimbursement. Consequently, these patients, especially those who are currently on the Medicaid roles, will not have a continuous access to their medications and will suffer the return of the psychiatric symptoms and most likely require psychiatric hospitalization. It will cost the Medicare program significantly more in terms of the adverse consequences than the minimal cost of including the anti-psychotics in the CAP program.

I would suggest a change to the proposed rule such that psychiatric drugs are included in the CAP program.

Sincere

J~cJueline M. Feldman,
Pafrick H. Linton Professor
Director, Division of Public Psychiatry
Department of Psychiatry and Behavioral Neurobiology
School of Medicine
University of Alabama at Birmingham

cc: Senator Richard Shelby
Senator Jeff Sessions

The University of Alabama at Birmingham Community Care Building' 908
South 20th Street Birmingham, Alabama 35294-2050' (205) 934-4108' FAX
(205) 975-8950

Submitter : **Ms. Lisa Blevins** **Date: 04/25/2005**

Organization : **Ms. Lisa Blevins**

Category : **Nurse Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

Please include PSYCHIATRIC DRUGS AND A MENTAL HEALTH DRUG CATEGORY!

Please include PSYCHIATRIC DRUGS IN PHASE I

Submitter : Mrs. BENITA WEBB

Date: 04/25/2005

Organization : Mrs. BENITA WEBB

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

PLEASE INCLUDE PSYCHIATRIC DRUGS AND A MENTAL HEALTH DRUG CATEGORY.

PLEASE INCLUDE PSYCHIATRIC DRUGS IN PHASE I

Submitter : Ms. LINDA OLIVER **Date:** 04/25/2005

Organization : Ms. LINDA OLIVER

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

PLEASE INCLUDE PSYCHIATRIC DRUGS AND A MENTAL HEALTH DRUG CATEGORY!

WE NEED PSYCH DRUGS IN PHASE I

Submitter : Dr. Edward Maxwell **Date:** 04/25/2005

Organization : University of Kentucky College ogf Medicine

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Psychotropic medications are commonly used by dually eligible clients who will be switched to Medicare prescription drug coverage from Medicaid under the new rule. It is very important that psychotropic drugs be included in the first phase of CAP. This should include all classes of psychotropics, both oral and parenteral forms. This must be done to assure uninterrupted access to these medications. Failure to assure such access could result in increased morbidity and mortality, not to mention an upsurge in very expensive hospitalization.

Submitter : Mrs. KIM SAMS **Date:** 04/25/2005

Organization : Mrs. KIM SAMS

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

PLEASE INCLUDE PSYCHIATRIC DRUGS AND A MENTAL HEALTH DRUG CATEGORY!

WE NEED PSYCHIATRIC DRUGS IN PHASE I

Submitter : Mrs. KATHY NAVE **Date:** 04/25/2005

Organization : Mrs. KATHY NAVE

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

PLEASE INCLUDE PSYCH DRUGS AND A MENTAL HEALTH DRUG CATEGORY!

WE NEED PSYCH DRUGS IN PHASE I

Submitter : **Kathleen Lynch** **Date: 04/25/2005**

Organization : **Kathleen Lynch**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

There are many problems with the CAP . I emplore you to reconsider the decision to implement this program. I have been an oncology nurse for 29 years, 23 of which have been in a private office. We have a system that works!! It is effecient, cost effective and patient friendly.
CAP requires the physician to be locked into the program for a year this is very unfair. We are concerned that decisions regarding treatment will be based on price and not efficacy. It will be almost impossible to maintain inventory on these patients. We do not have sufficient storage area. Keeping track of their drugs will be incredibly cumbersome. If drugs are not on hand patients will have to reschedule which is a burden to the patient as well as the family. Treatment changes will have to wait until the drug is furnished.
We will not be compensated for the handling, ordering or preparation for these medications.
It seems unreasonable that such drastic measures will be implemented with out any sort of trial period!
Please, reconsider your decision. This plan will be of no benefit to anyone.
Thank you,
Kathy Lynch

Submitter :

Date: 04/25/2005

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

As the Director of Operations for our practice it is my resposibility to run the business aspects of our practice. With over 30 years experience in business, I can say that any new regulation or operational change is never as smooth as some think and it is never as bad as some think. Cash flow is king in trying to manage the finances of an Oncology Practice and drug expenses are the major expenditure for most practices. Compassionate care for our patients is the daily goal of our Physicians and Staff. We have worked through the Medicare changes over the past two years and have no intention of making any change to our operation that would put our patient care at risk. The timing on making our decision on CAP is a serious concern because it is not lilely that all questions will have an answer by the deadline for our decsion. Also, as I understand the plan now, we will not be able to change our decision for a year. In looking at financial results on a monthly basis, we react to trends by making changes in our strategy or contracts as we determine that another method is preferable. C.O.A.and A.S.C.O. have listed the obvious questions about the plan but one thing is paramount. NO DECISION we ever make should have a negative impact on our patients in their fight against cancer. As with most major changes to anything,' The devil is in the details' If we decide to sign up for the CAP method of drug management, we must know a lot more than we do today about specifics rather than concepts. Life and Death issues must have clear answers irrespective of the cost.

Submitter : Constance Conway **Date:** 04/25/2005

Organization : Constance Conway

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

As an individual who is caring for a family member with cancer I am concerned about CAP. It seems to me that cancer clinics will be locked into chosen vendors for a long period of time despite the vendors' ability to provide quality drugs and deliver when the patient needs them. Also patients will have to return for treatment after their drugs are ordered. This will be a great inconvienence for me and my family. There doesn't seem to be a provision for emergency treatments that may need to be given as soon as possible. I also know that multiple drugs are used in my family member's treatment regimen. This will necessitate multiple drug vendors for one treatment protocol. It seems like this is an inflexible system that does not deal with the realities of patient care. It seems to force a multitude of visits to clinics for cancer victims and their families. Patients who are already medically fragile and very ill. Please take the time to fully understand the implications of CAP to community cancer clinics and the patients they serve before putting this into place. Thank you.

Submitter : Mr. Chris Lanford **Date:** 04/25/2005

Organization : Abilene Hematology Oncology Group, PA

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

It would be nice to be able to see a list of CAP vendors well in advance of the rule taking effect so we could make an informed decision on whether to go with a CAP vendor or continue with the ASP+6% reimbursement we currently have. Hopefully, we would be given several vendors in which to choose from. US Oncology is our biggest competitor and it would be a shame if we were forced to have to purchase from them.
If Cardinal and US Oncology complete their partnership, I can easily see that Cardinal would soon be paying the salaries of US Oncology pharmacists and these pharmacists would work in US Oncology Cancer Centers across America, preparing chemo for their own cancer center patients, then Cardinal would have a small staff of pharmacists located in their main office to mail out drugs prepared for other independent oncolgy practices. This would be extremely unfair in my opinion, bordering on a monopoly that would force to close independent oncology practices across the country.

Submitter : **Mrs. Judy Whitfield** **Date: 04/25/2005**

Organization : **Mrs. Judy Whitfield**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

I would like to make sure that CMS understands the reality of preparing and delivering chemotherapy and related cancer drugs. I believe that CAP is bad medicine and bad economics. It will risk patient care, impose extra costs and liability on community cancer clinics and cost MEDICARE more money.

Some specific concerns regarding CAP as currently structured include:
We are locked into the drug vendor we choose for an entire year regardless of their adherence to quality, delivery, etc.
Patients will be inconvenienced and have to return for treatment because drugs will have to ordered.
Multiple vendors may be supplying drugs that go into a treatment regimen, creating a logistical nightmare.
Community cancer clinics currently maintain one drug inventory. CAP will produce multiple inventories, possible individual patient inventories.
Aspects of CAP appear to violate pharmacy laws
CAP will produce additional administrative burden, which I doubt will be compensated by Medicare.

Submitter : Mr. Marshall Duny **Date: 04/25/2005**

Organization : Delta Oncology Associates, PC

Category : Individual

Issue Areas/Comments

1-15

Overview of the CAP

In its implementation of the Medicare Modernization Act of 2003 (MMA), the Centers for Medicare and Medicaid Services (CMS) has sought to more adequately cover the labor, supply, pharmacy, and other costs incurred in the administration of cancer-fighting drugs. Among the steps taken is the adoption of G codes to cover drug administration services and the creation of a demonstration project for 2005 that provided additional reimbursement.

As a result, 2005 Medicare reimbursement for cancer care services is considerably higher than pre-MMA rates. However, total reimbursement will drop dramatically on January 1, 2006, when the demonstration project is scheduled to end and the drug administration transitional factor will be zeroed out.

It has been calculated that the impact of these changes will translate into a $940 underpayment for drug administration services per Medicare beneficiary. Put another way, 2006 Medicare reimbursement for patient care services will cover only an estimated 50.09% of drug administration costs.

This problem is a key factor in the implementation of the Competitive Acquisition Program (CAP) in 2006. Under CAP, middlemen vendors will furnish drugs to physicians who choose to give up the traditional buy-and-bill model and select the CAP model instead. The vendors will be responsible for billing Medicare for the drugs, and the physicians will receive reimbursement only for drug administration services.

CMS expects CAP to appeal to those physicians ?who do not want to be in the drug procurement and drug coinsurance collection business? [70 Fed. Reg. 10750]. Indeed, statements made by CMS and CAP?s Congressional authors all reinforce the notion that CAP is intended to be an option that physicians may choose to adopt in place of the current buy-and-bill model. According to the MMA Conference Report produced by Congress, ?Conferees intend this choice to be completely voluntary on behalf of the physicians? [H. R. Conf. Rep. No. 108-391, 108th Cong., 1st Sess. 593 (2003)].

And yet, it is possible that neither CMS nor Congress has recognized that the viability of these two choices turns on the adequacy of reimbursement for drug administration services. Unless changes are made, many oncologists will face a loss under the buy-and-bill model, a loss that will be even greater should they opt to participate in CAP. This is because the only reimbursement they will receive under CAP is payment for drug administration services ? which will fall well below the cost of providing drug administration services.

In light of the reimbursement shortfall that looms on January 1, 2006, many cancer care specialists will face a very different choice than the one that Congress intended: continue to offer cancer care services to seniors (under buy-and-bill or CAP) and incur a significant net loss?or discontinue offering chemotherapy services to Medicare beneficiaries altogether. Sadly, both approaches threaten the community cancer care services on which millions of Americans now depend.

Congress has clearly stated its intent that patient access to community cancer care must be preserved because it is the source of convenient, cost-effective care for more than 4-out-of-5 American cancer patients. If CMS intends to abide by this intent, it must take additional steps to align Medicare reimbursement with the cost of drug administration services.

Because the level of needed fee schedule restructuring is significant, CMS may be unable to solve this pending crisis before the 2006 Physician Fee Schedule must be published. As a result, I urge CMS to extend the quality demonstration while it works to match drug administration cost and payments. Otherwise, both the CAP and the ASP models will be doomed to failure and many Medicare cancer patients likely will be forced back to hospitals for chemotherapy.

Claims Processing Overview

I am concerned that the proposed rule?s delivery standards could pose a significant risk of increased financial and clinical costs to cancer patients. Today, cancer care practices routinely maintain a drug inventory to meet their patients? treatment needs. This has enabled practices to accommodate changes in patients? treatment plans without requiring the patient to return for therapy on another day. Under CAP, however, this level of service could be difficult if not impossible to maintain.

If chemotherapy sessions must be rescheduled to wait for the delivery of the drug(s) that patients need, they will face additional coinsurance obligations for the repeat physician services. In addition, patients will face other financial burdens in the form of higher transportation costs and additional missed time from work. This situation may also mean missed work time and reduced productivity for family members and other caregivers who must bring beneficiaries to the rescheduled treatment sessions.

I recognize that Social Security Act 1847B(b)(5) and the proposed rule permit physicians to receive replacement product from their CAP vendors for drugs taken from the physician?s inventory. Even if CAP physicians had a sufficient inventory to draw from, this option appears too narrowly tailored to save most patients from having to undertake a return trip and bear the cost of an additional coinsurance payment. Specifically, the use of the replacement program is limited to situations where the physician builds a record to demonstrate all of the following to the local carrier: (1) the drugs were required immediately, (2) the physician could not have anticipated the patient?s need for the drugs, (3) the CAP vendor could not deliver the drugs in a timely manner, and (4) the drugs were administered in an emergency situation.

There are a few glaring problems with the inventory replacement option. First, neither the statute nor the proposed rule defines ?emergency.? Moreover, neither the proposed rule nor the preamble discussion explains what a physician would have to show to justify immediate need or how the local carrier will assess whether the physician could have anticipated the patient?s drug needs sufficiently far in advance to permit delivery via the CAP vendor. Aside from the risk that the claim for replacement drug will be denied by the local carrier, the administrative burden of building this record may discourage many physicians from using the inventory replacement option. The inventory replacement option also raises the question about whether commercial insurers are being asked to subsidize a portion of the drug costs for Medicare beneficiaries in CAP, since Medicare would not be paying a physician for the ordering, financing, inventorying and handling costs associated

with drugs borrowed from the practice?s inventory.

I are even more concerned about what this option could mean for patients, since it is not at all clear that oncology practices will be able to maintain full inventories after the implementation of CAP. Depending on their patient bases, the range of drugs that some practices would need for Medicare beneficiaries may not be the same as the drug inventory that the practice would stock for commercial patients. Moreover, if CAP encourages the proliferation of mandatory vendor imposition (MVI) programs among commercial carriers, it is likely that some practices may stop maintaining drug inventories altogether.

In sum, patients may be forced to pay both a financial and clinical price for treatment disruptions due to CAP, potentially exposing them to medical complications and increased emergency hospitalizations in addition to repeat visits and higher cost-sharing obligations.

GENERAL

GENERAL

It seems to me the legislation is intent on (1) Destroying the cancer care delivery system in the US. (2) Enriching the drug companies and (3) enriching the insurance companies at the expense of Oncology practices such as the one I work for.

Submitter : Dr. Ronald Lacey **Date:** 04/25/2005

Organization : Mid-Missouri Mental Health Center

Category : Physician

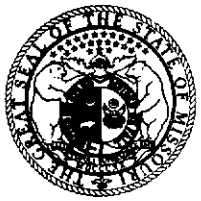
Issue Areas/Comments

GENERAL

GENERAL

see attached letter

CMS-1325-P-255-Attach-1.DOC



STATE OF MISSOURI
DEPARTMENT OF MENTAL HEALTH
DIVISION OF COMPREHENSIVE PSYCHIATRIC SERVICES
MID-MISSOURI MENTAL HEALTH CENTER
3 Hospital Drive Columbia, MO 65201-5296
573-884-1300

April 20, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
PO Box 8010
Baltimore, MD 21244-8010

To Whom It May Concern:

I writing to take the opportunity to comment on the Competitive Acquisition Program related to Part B Medicare. I am certain that many complex issues converge in the Medicare Modernization Act. However, my comments come from the perspective of a psychiatrist practicing in public sector psychiatry. Many of my patients suffer from serious and persistent mental disorders that significantly disrupt their lives. A significant percent of these individuals are served by Medicare benefits. Their access to treatment and medications are fundamental in stabilizing their lives and circumstances. I believe that it is essential that psychotropic medications, that include the newest medications and formulations such medications, be available to these Medicare beneficiaries through this new program.

Very truly yours,

Ronald L. Lacey, M.D.
Medical Director

Submitter : **Ms. Patricia Barnett** **Date: 04/25/2005**

Organization : **Eyetech Pharmaceuticals**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-256-Attach-1.DOC

CMS-1325-P-256-Attach-2.TXT

eyetech

3 Times Square, 12th floor • New York, New York 10036
Telephone: 212 824.3100 • Fax: 212 824.3101
www.eyetech.com

April 27, 2005

Mark McClellan, M.D., PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

Dear Dr. McClellan:

Thank you for the opportunity to provide comments on the proposed rule for the Medicare Part B Competitive Acquisition Program (CAP). Our company, Eyetech Pharmaceuticals, Inc., is a biopharmaceuticals company with a focus on the development of therapeutics to treat diseases of the eye.

We are enthusiastic about the introduction of the CAP and would like to offer support for its implementation. While the CAP may provide substantial benefits to those physician specialties that currently have large numbers of Part B covered drugs, we feel that the CAP can also be beneficial to those specialties with growing inventories of Part B covered drugs. As a company with a particular interest in ophthalmology, we have witnessed the demanding burdens physicians face in obtaining Medicare Part B covered drugs through the average sales price system (ASP). Part B "incident to" drugs are relatively new to ophthalmologists; however, their use is expected to continue to increase. The CAP is intended to bring savings and efficiency to the purchase of Part B covered drugs, and ophthalmologists want to be part of the system of the future, not the system of the past.

In response to the solicitation of comments, we will offer our views on the following: the categories of drugs and the phase-in of categories into the CAP, the scope of the competitive acquisition areas, the potential introduction of new drugs under the CAP, and the criteria for CAP vendors. We hope that our professional perspective will prove valuable to you as you prepare to implement this important program.

Categories of Drugs and Phasing-in Plan

Eyetech strongly supports creating a drug category for ophthalmology. We have been encouraged by our discussions with ophthalmologists and believe they are eager to participate in the CAP and utilize this option to administer drugs to beneficiaries. As you are aware, ophthalmology drugs are typically administered by physicians, and therefore, are covered under Medicare Part B. Currently, the number of Part B covered ophthalmology drugs is limited; however, there are a number of drugs in clinical development in response to the anticipated dramatic growth in the elderly population and the growing incidences of eye disease. Today, beneficiaries are faced with very few avenues in which to receive ophthalmology drugs. It is imperative that they have the access and ability to receive the necessary treatments for eye diseases. By including a category of ophthalmology drugs under the CAP, Medicare will be addressing a critical, unmet need of its beneficiaries and physicians.

As the proposed rule states, the Secretary of Health and Human Services (HHS) has the discretion to phase-in drug categories under the CAP. We firmly believe that ophthalmology drugs should be included in the initial categories for the CAP beginning on January 1, 2006. The prevalence of debilitating eye diseases, such as macular degeneration and diabetic edema, are escalating and the CAP is an opportunity to address this serious need now. In addition, the proposed rule states that by phasing-in drugs by a physician specialty, such as ophthalmology, CMS will be able to evaluate and address operational issues of the CAP for smaller Medicare Part B covered drug categories. We are conscious of the significant percentage of Part B covered drugs that are administered by oncologists. We are confident that should oncology by included in the initial phases of the CAP, it would be beneficial to complement such a large segment of Part B drugs with a specialty, such as ophthalmology, to evaluate the performance of the program on two scales.

Competitive Acquisition Areas

As noted in the proposed rule, the Secretary of HHS has the authority to establish geographic region(s) for the CAP. We are in support of a National Competitive Acquisition Area (CAA). We believe that a National CAA is aligned with meeting the goals of the CAP. Further, we share the view that this plan would encourage more vendors to participate in the CAP because of the access to a significant market share of physicians and beneficiaries. In addition, it will enable the Centers for Medicare & Medicaid Services (CMS), physicians, and vendors to dramatically reduce the amount of time and capital spent addressing administrative tasks.

Introduction of New Drugs into the CAP

Physicians that are under the CAP should be able to purchase new drugs as they enter the marketplace, and more importantly, beneficiaries should have access to the best new treatments. The proposed rule briefly mentions the introduction of new drugs into the CAP. We share the opinion that CMS should make adjustments to "single price," following the introduction of new drugs into a category. We also are in support of adjustments occurring quarterly. We recognize the potential administrative burden on frequent "single price" adjustments, and in this regard, we support the limited exceptions outlined in the proposed rule, particularly for the introduction of new drugs.

Impact of CAP Vendor-Negotiated Pricing

Neither the law nor the proposed regulation address the impact of a CAP vendor-negotiated price on other CMS and government programs. For example, the ASP payment methodology explicitly notes that Medicaid rebates are not part of the calculation. Similarly, CAP-negotiated prices should be excluded from the calculations for Medicaid AMP or Best Price, Medicare ASP, 340B, FFS and other government programs pricing. Ambiguity on this issue may discourage manufacturer participation in CAP. We therefore urge CMS to adopt the position, well in advance of CAP's launch date, that CAP-negotiated prices will not affect CMS and other government program pricing.

Vendor Criteria

We are in strong support of criteria that include high standards of excellence, ethical practice, fiscal responsibility, product security, and integrity. Eyetech believes that the vendors participating in the CAP must meet the highest standards of performance. It is imperative that the interests of the patients and physicians are considered in every aspect of selecting vendors. We understand the administrative challenges physicians face under the ASP system and we support the CAP, in part, because it will enable physicians to focus more on their ability to deliver the best service to beneficiaries. However, we feel that this benefit to physician care should not compromise standards for vendors. We applaud CMS for establishing a high benchmark for this aspect of the CAP.

eyetech

We are confident that the CAP will meet the goals of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) and ultimately provide better care and access to essential drugs for beneficiaries. As CMS moves forward with implementing the CAP and other aspects of the MMA, we hope that you will consider Eyetech Pharmaceuticals, Inc. a valued resource. Our industry experience, coupled with a commitment to the highest standards, uniquely qualify Eyetech as a leader in the pharmaceutical arena. We are grateful for the opportunity to share our views on this issue and thank you for your consideration.

Sincerely,

Pat Barnett
Director of Reimbursement and Health Policy
Eyetech Pharmaceuticals, Inc.

Submitter : **Ms. Carreen Huffman** **Date: 04/25/2005**

Organization : **Center for Cancer and Blood Disorders**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

The Cap program is an impractical idea which is neither patient nor physician friendly. It imposes unneccessary additional liablility on community oncology centers along with a bad way of doing business. What if you select a CAP vendor and their performance is below par and creates treatment problems which are critical to the well being of the patient. Chemotherapy treatment should be left in the hands of the professional and not turned into a brown bag situation left to the patients and substandard Cap providers that are mostly owned by commercial payors who cannot even pay a claim correctly. The administrative burden/liability to the clinics I am certain will not be considered nor compensated.

What happens when the Cap provider cannot collect the co-pay from the patient and then cuts them off, do we then stop treatment since we have no meds or do we as a physicians absorb the loss and get meds to make sure we take care of our patients? Where is the safety net?

Submitter :

Date: 04/25/2005

Organization :

Category : Other Health Care Professional

Issue Areas/Comments

1-15

Overview of the CAP

There seems to be many unanswered questions about how CAP is to be implemented and then carried out. Therefore the very aggressive timeframe for beginning the program is unrealistic, and will only serve to amplify the existing problems.

Statutory Requirements Concerning Claims Processing

CMS' statement that the administrative requirements offered by CAP are not any different than in the current reimbursement model is a gross misrepresentation. These requirements will result in material operational changes, and a corresponding increase in cost.

Categories of Drugs to be Included under the CAP

I am a proponent of testing the program on a limited set of drugs and biologicals. This will provide the opportunity to troubleshoot any problems with the least impact on patient care.

Competitive Acquisitions Areas

Regional market areas will serve the system the best, in my opinion. This will facilitate efficient delivery, relevant economics, and practical administrative policies.

Submitter : Mr. Todd Stevens **Date:** 04/25/2005

Organization : Louisiana Hematology Oncology Associates

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

As a practice manager for a community cancer clinic (Louisiana Hematology Oncology Associates), I am opposed to this rule. It is my understanding that the CAP program was developed without input from practicing community oncologists/clinics. As is, the CAP program appears to be a regulatory burden with no benefit to the process of providing care to cancer patients. It is my opinion that CAP is not the answer to the drug payment problem and implementation of the rule will cause Pharmaceuticals to have little if any incentive to bid drugs; will increase costs to the Medicare system; and will cause additional administrative burdens and liability for cancer clinics. Not only will oncologists have to submit individual claims but they will also have to track inventory for each patient; thus requiring them and their staff to anticipate emergencies and the changing needs of their patients to ensure that the appropriate drug and dosage is available. Instead, CMS should reform the ASP drug reimbursement system in such a way that will enable oncologists to manage the needs of their patients. Additionally, oncologists should receive remuneration for the extensive cognitive effort and time that is required of them and their staff to properly manage the delivery of modern cancer care. A more prudent approach to assure the nation's cancer patients continue to recieve well coordinated care would be to extend the demonstration project through 2006 in order to develop an appropriate reimbursement model for oncologists that values their time, effort, knowledge and contribution to fighting and winning the war on cancer.

Submitter : **Date: 04/25/2005**

Organization : **Infectious Diseases Society of America**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1325-P-260-Attach-1.DOC

April 26, 2005

Mark McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Comments on Proposed Rule [Docket No. CMS-1325-P]: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B

Dear Dr. McClellan:

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Competitive Acquisition Program (CAP) Proposed Rule (proposed rule) published on March 4, 2005.

Before addressing the CAP, we must first note that IDSA's physician members are experiencing serious problems in acquiring many antibiotics and other products at or below the Average Sales Price (ASP). IDSA submitted physician cost data to CMS in a letter dated March 7, 2005, which clearly illustrates the on-going problem. We have not yet heard back from CMS about how the agency intends to fix this problem. However, the problems with the flawed ASP program underscore the importance of ensuring the implementation of a viable CAP for infectious diseases (ID) physicians providing in-office drug therapy.

IDSA appreciates the time CMS staff has devoted to the Medicare Prescription Drug, Improvement, and Modernization Act's implementation, including the restructuring of drug infusion and injection codes, the implementation of the ASP methodology, and most recently, the issuance of the CAP proposed rule for public comment. IDSA, through its comments, is eager to assist CMS in creating a CAP final rule that will better ensure Medicare beneficiaries continue to have access to life-saving drugs and biologicals in the physician office-based setting. With this in mind, IDSA will comment on the following issues raised by the proposed rule:

Claims Processing Overview

- The definition of "emergency" situations, including what circumstances constitute an emergency, needs to be more clearly outlined in the final rule. The unique role that ID specialists play in quickly responding to and managing acute, life-threatening infectious agents in their local communities necessitates that the CAP final rule accurately define what constitutes an "emergency."

- A system needs to be put in place to obtain drugs with minimal delay. Infectious diseases specialists may not be able to maintain pre-existing inventories of every drug they might possibly need on hand at all times.
- IDSA favors a multi-specialty phase-in of the CAP using one or two widely used drug categories.

Categories of Drugs to be Included Under the CAP

- Physicians should be able to opt in and out of the CAP on a category specific basis.
- Categories should be limited in size to include functionally similar drugs (or particular families of drugs) to allow flexibility in obtaining drugs and biologicals through the CAP.

Competitive Acquisition Areas

- IDSA favors competitive acquisition areas that factor in both population density and geographic boundaries.

Collection of Information Requirements

- IDSA believes that the clerical and administrative resources needed to order, maintain, and file claims for per-patient drug doses will be overly burdensome to physicians. Alternatives must be considered.

BACKGROUND

IDSA represents nearly 8,000 physicians and scientists devoted to patient care, education, research, and community health planning in infectious diseases. The Society's members focus on the epidemiology, diagnosis, investigation, and treatment of infectious diseases as well as strive to prevent them in the U.S. and abroad. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, those with cancer or transplants who have life-threatening infections caused by unusual microorganisms, food poisoning, HIV/AIDS, and new and emerging infections, such as severe acute respiratory syndrome (SARS).

CLAIMS PROCESSING OVERVIEW

Infectious diseases specialists must quickly react to and treat a variety of conditions in their office-based practices that require life saving antibiotics and antivirals to be readily available. Such situations may range from an *Escherichia coli* H7:0157 outbreak in a small town to an individual case of methicillin-resistant *Staphylococcus aureus* (MRSA) that has been referred to an infectious diseases specialist late on a Friday afternoon by a local physician. Infectious diseases specialists frequently encounter "emergency" situations where lifesaving drugs are needed immediately and on any given day of the week including Saturday and Sunday. As such, IDSA and its members seek clarification as to what constitutes an "emergency" use of drugs under the CAP. IDSA believes strongly that the definition of "emergency" situations in the physician office-based setting should include drugs that are needed on an immediate basis within the context of the typical infectious diseases practice. Alternatively, CMS should provide other terminology and processes that encompass the medical needs of a typical infectious diseases specialist's practice. Specific examples include: 1) new patients who need to be immediately started on antibiotics for infections; or 2) existing patients who require

immediate modification of their treatment regimen due to an allergic or other adverse reaction or new circumstances such as a new pathogen or updated culture result.

In many cases, when ID specialists need drugs immediately to prevent complications and/or costly hospital stays (and have no existing inventory), a 24-hour shipping period is not prompt enough. A provision should be included within the CAP final rule to require same day drug deliveries or to allow for immediate drug acquisition when the diagnosing physician can show a clear and present danger to the patient's health and well-being if the drug is not administered immediately. Such a provision could be modeled after the existing "furnish as written" provision, which allows physicians to "obtain a drug under the ASP methodology" in certain situations. Without such a provision, Medicare ultimately will be forced to pay for unnecessary hospital stays for patients that could have been treated more cost effectively in ID physicians' offices. In addition, care must be taken to ensure that whatever mechanism is implemented is of minimal burden to both the physician and patient.

Finally, under claims processing overview, CMS sought comment about how the CAP should be phased-in. IDSA favors a multi-specialty phase-in of the CAP using one or two widely used drug categories. Not only would this approach allow the maximum number of physicians and specialties to become familiar with the CAP, but also, it would allow the vendors to develop experience across multiple specialties and throughout their contracted service areas. We feel that antibiotics represent ideal drugs for an initial phase in of the CAP, since virtually all physicians, regardless of specialty, use them.

CATEGORIES OF DRUGS TO BE INCLUDED UNDER THE CAP

IDSA supports the rule's premise that physicians should have the freedom to opt in or out of the CAP on a category specific basis. We also favor categories that are narrowly configured and align functionally similar drugs. With this in mind, IDSA believes that drug categories should be modeled after the pharmacologic classes established in the United States Pharmacopeia's (USP) drug formulary model guidelines in December 2004. In the case of antibiotics classes, cephalosporins, penicillins, macrolides, and quinolones would occupy their own drug categories. This would allow physicians maximum flexibility to best meet the needs of their patients and the physician's business model.

IDSA also believes strongly that vendors should be allowed to add new drugs to categories during the contract year. The health and well-being of patients, in many cases, depends on physicians' ability to acquire the newest and most effective drugs. However, vendors should not be permitted to substitute or delete drugs throughout the year. Thus, physicians electing to acquire drugs through the CAP will have the assurance of knowing that no substitutions or deletions will be made during the contract year.

COMPETITIVE ACQUISITION AREAS

IDSA favors competitive acquisition areas that will provide for the most efficient and timely delivery of drugs to physicians (and their patients). While statewide areas may work well in densely populated states, an efficient and timely delivery of drugs will be much more difficult in states with smaller populations and/or geographic boundaries. The areas need to be defined such that less densely populated states and/or states with difficult geography are not placed at a disadvantage. Vendors participating in the CAP will most likely have pre-existing shipping

networks established in multiple states (since they will have to generate enough volume to justify small profit margins). As such, we feel that competitive acquisition areas that factor in both population density and geographic boundaries will allow for the most timely and efficient delivery of drugs and biologicals.

COLLECTION OF INFORMATION REQUIREMENTS

In the proposed rule, the costs (to physicians) associated with the CAP are dismissed because CMS believes that maintaining separate physical inventories of CAP and non-CAP drugs will not require significant resources. However, the proposed rule does require physicians to maintain a separate electronic or paper inventory for each CAP drug obtained. Additionally, physicians are required to order and file claims for per patient doses of drugs. The requirements to order, track, and file claims on per patient doses of drugs will be both expensive and burdensome for physician practices. There is no way for physicians to recoup these costs. As an alternative to the electronic and paper inventory maintenance requirement, we suggest that CMS track drug utilization through a combination of vendor invoices and the administration claims submitted by physicians to CMS. Invoices from the vendor of drugs shipped to a physician can be matched with the administration claims to allow tracking of drug usage. This would eliminate the costly maintenance of separate electronic and/or paper inventories for CAP drugs and biologicals.

CONCLUSION

IDSA appreciates this opportunity to comment on CMS' Proposed CAP Rule. We strongly believe that infectious diseases physicians need a viable alternative to the flawed ASP methodology for acquiring drugs and biologicals. There are serious problems in the proposed rule and we believe that the final rule should incorporate our changes to better ensure Medicare beneficiaries continued access to life-saving drugs and biologicals in physicians' office setting.

If you have any questions concerning this matter, please contact Robert J. Guidos, J.D., IDSA's Director of Public Policy and Government Relations, at 703-299-0200.

Sincerely,

Walter E. Stamm, MD
President

Submitter : Dr. Dwight Owens **Date:** 04/25/2005

Organization : CMHC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please be advised that if this bill is passed, please include Mental health drugs, specifically injectables, at the implementation of the program. This will be very important for most of the indigent patients that we serve.

Submitter : Dr. Robert Woodburn **Date:** 04/25/2005

Organization : Cancer Health Treatment Centers

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-262-Attach-1.DOC

April 25, 2005

Centers for Medicare and Medicaid Services
Dept. of Health & Human Resources
ATTENTION: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: Comments put forth by the American Society of Clinical Oncology (ASCO) on the proposed rules governing the Competitive Acquisition Program (CAP) for drug administered in physician offices, which were published in the Federal Register March 4, 2005.

We the undernamed support and agree with the comments put forth by ASCO and request you provide full consideration to their comments made.

Sincerely,

Robert T. Woodburn, M.D.
Pimpa J. Tara, M.D.
Virginia Tan Tabib, M.D.
Cheryl Morgan-Ihrig, M.D.
M.Y. Ali, M.D.
J.P. Sanghvi, M.D.
B. Keralavarma, M.D.
Murugavel Muthusamy, M.D.
George Sloan, M.D.

Cancer Health Treatment Centers
8127 Merrillville Road
Merrillville, IN 46410

Submitter : Dr. Pimpa Tara **Date:** 04/25/2005

Organization : Cancer Health Treatment Centers

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-263-Attach-1.DOC

April 25, 2005

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ATTENTION: CMS-1325-P
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Murugavel Muthusamy, M.D.
George Sloan, M.D.

Cancer Health Treatment Centers
8127 Merrillville Road
Merrillville, IN 46410

Submitter :

Date: 04/25/2005

Organization :

Category : Physician

Issue Areas/Comments

1-15

Overview of the CAP

potential disaster for providers and patients - financial and logistic nightmare

Submitter : Mrs. Cynthia Israel **Date:** 04/25/2005

Organization : Cancer Care Associates

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I understand the need to change our drug delivery system in regards to Medicare and the rising of drug costs on the goverment. Although it has been difficult as a nurse manager in oncology to keep up with the changes and keep patients safe and the practices out of the red. It seems that decisions are being made and implemented before Medicare themselves even understands the new system. Much less passing on and explaining the new system to its users. I would think things would go over much smooother with your constituents if you both understood the new systems/changes and explained them in detail PRIOR to rolling them out.
Thank you for your time,
Cynthia E. Israel RN OCN
Sterling Heights MI 48310

Submitter : Mrs. Tuesday Trott **Date:** 04/25/2005

Organization : Lower Shore Clinic

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Injectable medications. See attachment, please.

Submitter : Mrs. Tuesday Trott **Date:** 04/25/2005

Organization : Lower Shore Clinic

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Injectable medications. Please see attached.

CMS-1325-P-267-Attach-1.DOC

April 23, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Part B Competitive Acquisition Program, Categories of Drugs to be Included under CAP

Dear Dr. McClellan:

I am writing in strong support of the proposed rule recently issued by the Centers for Medicare and Medicaid Services (CMS) that addresses implementation of the Competitive Acquisition Program (CAP). This program has tremendous potential to benefit individuals with severe and persistent mental illnesses for whom injectable medications can help maintain adherence to drug regimens, treatment that is life-saving and essential to successful rehabilitation outcomes. We urge that injectable antipsychotic medications be included in the initial phase of CAP implementation.

Advantages of Injectable Psychiatric Medications

In 2003, the final report of the President's New Freedom Commission on mental health declared that recovery – helping individuals overcome the disabling aspects of mental illnesses – is the overarching goal of the U.S. mental health system. Addressing the means for attaining this goal, the report stated, "To achieve the promise of community living for everyone, new service delivery patterns and incentives must ensure that every American has easy and continuous access to the most current treatments and best support services." In implementing the CAP program, CMS has an opportunity to make a significant contribution to fulfilling the goals of the federal New Freedom Initiative by facilitating patient access to important psychiatric medications.

Patient noncompliance with psychotropic medication regimens is similar to that for patients who take medications for somatic illnesses. A review of the literature has found that most patients probably only take 33 – 94 percent of their prescribed drugs, with the median being about 50 percent for long-term therapy, while a sizeable percentage are wholly noncompliant.[1] For people with schizophrenia and severe mood disorders, noncompliance with medications often results in the relapse of acute symptoms, frequently resulting in negative outcomes such as rehospitalization, loss of employment/housing, and suicide. These negative consequences for the patient are compounded by a parallel negative impact on the service delivery system: costs escalate as outpatient treatment is stymied, the use of emergency facilities increases, and hospital stays are more frequent and longer.

[1] Morris LS, Schulz RM. Patient compliance—an overview. J Clin Pharm Ther 1992, 17:283-95.

The use of injectable antipsychotics has been recognized as an important, evidence-based practice that addresses the noncompliance of issue of many with schizophrenia. In addition, a new type of psychotropic medications show tremendous promise in addressing the issue of partial compliance among people with mental illnesses. These new medications are injectable, but do not have the side effect profile of older injectable depot psychotropics that consumers found objectionable, including lingering pain after the injection, sedation, and other effects. While a number of the new injectable medications are currently in development (including an antidepressant), one antipsychotic, an injectable form of risperidone, has been employed successfully in community-based settings for about a year, and it has shown great promise in treating schizophrenia.

The Schizophrenia Patient Outcomes Research Team (PORT) treatment recommendations, considered one of the most important practice guidelines for the treatment of schizophrenia, find that the older injectables are an important therapy for schizophrenia, stating that depot injectables should be "strongly considered for persons who have difficulty complying with oral medication..." The emerging evidence for the use of risperidone long-acting injection seems to indicate that the new injectable antipsychotics may offer significant clinical advantages to the older depot injectables, in addition to addressing the issue of noncompliance. Compliance is a significant issue in the treatment of schizophrenia, with 50 – 70 percent of all patients being only partially compliant in the first two years of treatment. A survey of studies found that noncompliance was associated with a risk of relapse that is 3.7 times greater than that for compliant patients.[2]

Studies have found that use of long-acting injectable risperidone is associated with fewer and shorter hospitalizations[3] and improved functioning and quality of life.[4] Given the promise of these new injectable medications to improve outcomes for patients and reduce healthcare costs, and the recognition of the use of injectable depot medications as an evidence-based practice, we believe that CMS should make consumer access to injectable antipsychotic medications an urgent priority. As other new injectable psychotropics become available, we suggest that CMS prioritize efforts to enhance consumer access to these drugs.

Current Obstacles Faced by Providers Using Injectable Psychiatric Medications

Unfortunately, community mental health centers (CMHCs) and other multi-service community providers, which serve a large number of people with severe mental illnesses that are eligible for both Medicaid and Medicare, face serious obstacles in providing injectable medications. As safety-net providers, CMHCs are very often heavily burdened treatment settings that lack sophisticated information technology and a sufficient level of administrative staffing. For example, to provide the new injectable antipsychotic risperidone to patients, CMHCs must first purchase the medication, and then seek reimbursement from both Medicare (which makes only

[2] Fenton WS, Blyler CR, Heissen RK. Determinants of medication compliance in schizophrenia. Schizophr Bull. 1997, 637-651.

[3] Leal A, Rosillon D, Mehnert A et al. Healthcare resource utilization during 1-year treatment with long-acting injectable risperidone, Pharmacoepid Drug Safety, 2004, 13: 811-816.

[4] Nasrallah HA, Duchesne I, Mehnert A, et al. Health-related quality of life in patients with schizophrenia during treatment with long-acting injectable risperidone. J Clin Psychiatry 2004, 65:531-536.

partial payment for mental health drugs) and Medicaid. Providers then bear the administrative burden of tracking the claims and the financial risk of receiving incomplete payment from one or both payers. This burden has become an impediment to expanding access to this medication to the full range of patients who could benefit from it. In some cases, CMHCs will only provide the medication to patients that are solely Medicaid beneficiaries. When injectable antipsychotics are included in the Medicare CAP program, this substantial impediment will be removed, as providers would have the option to obtain the medications from a drug vendor that will handle reimbursement from Medicare. Helping providers expand access to this medication will bring great benefit to our patients with schizophrenia.

From a brief review of the proposed rule, it appears that CMS may view oncology medications as the primary medication category to be included in the initial phase of CAP. CAP also has the potential to bring new psychiatric therapies into wider use and to significantly improve the quality of care for some of the most vulnerable people in our society – helping to "achieve the promise" of the New Freedom Initiative for people with psychiatric disabilities. We urge you to include coverage of antipsychotic injectable medications in the drug categories that compose the initial phase of CAP implementation.

Sincerely,

Tuesday Trott
Administrator
Lower Shore Clinic

Submitter : Dr. E. Bautista **Date:** 04/25/2005

Organization : Lower Shore Clinic

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-1325-P-268-Attach-1.DOC

April 23, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Part B Competitive Acquisition Program, Categories of Drugs to be Included under CAP

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Advantages of Injectable Psychiatric Medications

In 2003, the final report of the President's New Freedom Commission on mental health declared that recovery – helping individuals overcome the disabling aspects of mental illnesses – is the overarching goal of the U.S. mental health system. Addressing the means for attaining this goal, the report stated, "To achieve the promise of community living for everyone, new service delivery patterns and incentives must ensure that every American has easy and continuous access to the most current treatments and best support services." In implementing the CAP program, CMS has an opportunity to make a significant contribution to fulfilling the goals of the federal New Freedom Initiative by facilitating patient access to important psychiatric medications.

Patient noncompliance with psychotropic medication regimens is similar to that for patients who take medications for somatic illnesses. A review of the literature has found that most patients probably only take 33 – 94 percent of their prescribed drugs, with the median being about 50 percent for long-term therapy, while a sizeable percentage are wholly noncompliant.[1] For people with schizophrenia and severe mood disorders, noncompliance with medications often results in the relapse of acute symptoms, frequently resulting in negative outcomes such as rehospitalization, loss of employment/housing, and suicide. These negative consequences for the patient are compounded by a parallel negative impact on the service delivery system: costs escalate as outpatient treatment is stymied, the use of emergency facilities increases, and hospital stays are more frequent and longer.

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Sincerely,

Tuesday Trott
Administrator
Lower Shore Clinic

Submitter : Mrs. Billie Jo Ross **Date:** 04/25/2005

Organization : Mental Health Asssociation of the Lower Shore

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

see attached.

CMS-1325-P-269-Attach-1.DOC

April 23, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Part B Competitive Acquisition Program, Categories of Drugs to be Included under CAP

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The Schizophrenia Patient Outcomes Research Team (PORT) treatment recommendations, considered one of the most important practice guidelines for the treatment of schizophrenia, find that the older injectables are an important therapy for schizophrenia, stating that depot injectables should be "strongly considered for persons who have difficulty complying with oral medication..." The emerging evidence for the use of risperidone long-acting injection seems to indicate that the new injectable antipsychotics may offer significant clinical advantages to the older depot injectables, in addition to addressing the issue of noncompliance. Compliance is a significant issue in the treatment of schizophrenia, with 50 – 70 percent of all patients being only partially compliant in the first two years of treatment. A survey of studies found that noncompliance was associated with a risk of relapse that is 3.7 times greater than that for compliant patients.[2]

Studies have found that use of long-acting injectable risperidone is associated with fewer and shorter hospitalizations[3] and improved functioning and quality of life.[4] Given the promise of these new injectable medications to improve outcomes for patients and reduce healthcare costs, and the recognition of the use of injectable depot medications as an evidence-based practice, we believe that CMS should make consumer access to injectable antipsychotic medications an urgent priority. As other new injectable psychotropics become available, we suggest that CMS prioritize efforts to enhance consumer access to these drugs.

Current Obstacles Faced by Providers Using Injectable Psychiatric Medications

Unfortunately, community mental health centers (CMHCs) and other multi-service community providers, which serve a large number of people with severe mental illnesses that are eligible for both Medicaid and Medicare, face serious obstacles in providing injectable medications. As safety-net providers, CMHCs are very often heavily burdened treatment settings that lack sophisticated information technology and a sufficient level of administrative staffing. For example, to provide the new injectable antipsychotic risperidone to patients, CMHCs must first purchase the medication, and then seek reimbursement from both Medicare (which makes only

[2] Fenton WS, Blyler CR, Heissen RK. Determinants of medication compliance in schizophrenia. Schizophr Bull. 1997, 637-651.
[3] Leal A, Rosillon D, Mehnert A et al. Healthcare resource utilization during 1-year treatment with long-acting injectable risperidone, Pharmacoepid Drug Safety, 2004, 13: 811-816.
[4] Nasrallah HA, Duchesne I, Mehnert A, et al. Health-related quality of life in patients with schizophrenia during treatment with long-acting injectable risperidone. J Clin Psychiatry 2004, 65:531-536.

partial payment for mental health drugs) and Medicaid. Providers then bear the administrative burden of tracking the claims and the financial risk of receiving incomplete payment from one or both payers. This burden has become an impediment to expanding access to this medication to the full range of patients who could benefit from it. In some cases, CMHCs will only provide the medication to patients that are solely Medicaid beneficiaries. When injectable antipsychotics are included in the Medicare CAP program, this substantial impediment will be removed, as providers would have the option to obtain the medications from a drug vendor that will handle reimbursement from Medicare. Helping providers expand access to this medication will bring great benefit to our patients with schizophrenia.

From a brief review of the proposed rule, it appears that CMS may view oncology medications as the primary medication category to be included in the initial phase of CAP. CAP also has the potential to bring new psychiatric therapies into wider use and to significantly improve the quality of care for some of the most vulnerable people in our society – helping to "achieve the promise" of the New Freedom Initiative for people with psychiatric disabilities. We urge you to include coverage of antipsychotic injectable medications in the drug categories that compose the initial phase of CAP implementation.

Sincerely,

Billie Jo Ross
President
Mental Health Association of the Lower Shore

Submitter : **Dr. Harvey Neiman** **Date: 04/25/2005**

Organization : **American College of Radiology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-270-Attach-1.DOC

American College of Radiology

April 25, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850
File Code: CMS-1325-P

Re: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Proposed Rule

Dear Administrator McClellan:

The American College of Radiology (ACR), representing over 32,000 physicians specializing in radiology, radiation oncology, interventional radiology and nuclear medicine, would like to thank the Centers for Medicare and Medicaid Services (CMS) for this opportunity to provide comments on the proposed rule to implement the Competitive Acquisition Program (CAP) for outpatient drugs and biologicals covered under Medicare Part B (70 Fed. Reg. 10746, March 4, 2005). Our comments will focus on the section of the proposed rule that addresses "Categories of Drugs to be Included under the CAP" and the potential impact of this section on contrast agents, the drugs utilized by radiologists for medical imaging purposes.

Background

Section 303 (d) of the Medicare Modernization Act amends Title XVIII of the Act by adding a new section 1847B that requires the implementation of a competitive acquisition program (CAP) for Medicare Part B drugs and biologicals not paid on a cost or prospective payment system basis. Beginning with drugs administered on or after January 1, 2006, physicians will be given a choice between:

1. buying and billing these drugs under the average sales price (ASP) system, or
2. obtaining these drugs from vendors selected in a competitive bidding process.

As described by CMS in the proposed rule, the CAP may provide opportunities for Federal savings to the extent that aggregate bid prices are less than 106 percent of ASP. In addition, the CAP is designed to reduce the financial burden on physicians associated with employing working capital and bearing financial risk in the event of non-payment for drugs. The CAP also eliminates the need for physicians to collect coinsurance on CAP drugs from Medicare beneficiaries.

Categories of Drugs to be Included under the CAP

Section 1847B(a)(1)(B) of the Social Security Act (SSA) gives CMS the authority to phase-in categories of Part B drugs that would be offered under CAP. In the proposed rule, CMS identifies three major

agent that the physicians ordinarily would have selected, based on the unique circumstances of individual patients.

3. For the payment of a new drug or biological under the CAP, CMS proposes to apply the payment amount established under the ASP methodology until the next annual update of the payment amounts established under the CAP. Since contrast agents are constantly advancing and changing, new contrast agents may not be readily available if there are any administrative delays in the creation of new HCPCS codes under the CAP process.

The ACR appreciates the opportunity to comment on the proposed rule. We will continue to follow this issue; and, we look forward to continued dialogues with CMS officials. Should you have any questions on the items addressed in this comment letter, or with respect to radiology and radiation oncology, please contact Carisia Switala at the ACR. Carisia may be reached at 1-800-227-5463 ext. 4587 or via email at CarisiaS@acr.org. Also, should CMS decide to proceed and include contrast agents under CAP, regardless of the above comments, we respectfully request that CMS discuss this with us before implementing such a change.

Respectfully Submitted,

[Endorsed copy to follow]

Harvey L. Neiman, MD, FACR
Executive Director

cc: John A. Patti, MD, FACR, Chair, ACR Commission on Economics
Arthur Segal, MD, FACR, Chair, ACR Committee on Drugs and Contrast Media
Pamela J. Kassing, ACR
Rachel S. Kramer, ACR
Margaret Wyatt, ACR

Submitter : Miss. Laurie Rockelli **Date:** 04/25/2005

Organization : Lower Shore Clinic

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

please see attached.

CMS-1325-P-271-Attach-1.DOC

April 23, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Part B Competitive Acquisition Program, Categories of Drugs to be Included under CAP

Dear Dr. McClellan:

I am writing in strong support of the proposed rule recently issued by the Centers for Medicare and Medicaid Services (CMS) that addresses implementation of the Competitive Acquisition Program (CAP). This program has tremendous potential to benefit individuals with severe and persistent mental illnesses for whom injectable medications can help maintain adherence to drug regimens, treatment that is life-saving and essential to successful rehabilitation outcomes. We urge that injectable antipsychotic medications be included in the initial phase of CAP implementation.

Advantages of Injectable Psychiatric Medications

In 2003, the final report of the President's New Freedom Commission on mental health declared that recovery – helping individuals overcome the disabling aspects of mental illnesses – is the overarching goal of the U.S. mental health system. Addressing the means for attaining this goal, the report stated, "To achieve the promise of community living for everyone, new service delivery patterns and incentives must ensure that every American has easy and continuous access to the most current treatments and best support services." In implementing the CAP program, CMS has an opportunity to make a significant contribution to fulfilling the goals of the federal New Freedom Initiative by facilitating patient access to important psychiatric medications.

Patient noncompliance with psychotropic medication regimens is similar to that for patients who take medications for somatic illnesses. A review of the literature has found that most patients probably only take 33 – 94 percent of their prescribed drugs, with the median being about 50 percent for long-term therapy, while a sizeable percentage are wholly noncompliant.[1] For people with schizophrenia and severe mood disorders, noncompliance with medications often results in the relapse of acute symptoms, frequently resulting in negative outcomes such as rehospitalization, loss of employment/housing, and suicide. These negative consequences for the patient are compounded by a parallel negative impact on the service delivery system: costs escalate as outpatient treatment is stymied, the use of emergency facilities increases, and hospital stays are more frequent and longer.

[1] Morris LS, Schulz RM. Patient compliance—an overview. J Clin Pharm Ther 1992, 17:283-95.

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Sincerely,

Laurie Rockelli, APRN, BC
Clinical Nurse Specialist

Submitter : **Dr. Dwight Oldham** **Date: 04/25/2005**

Organization : **Lynchburg Hematology Oncology Clinic, Inc.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

CAP is an abysmal plan that will critically impair cancer care. It?s clear that the intricacies of cancer treatment are unknown to the legislators designing this CAP program. It?s clear the plan will add barriers and delays to patients requiring care and unimaginable costs and risks to practices.

1. The inflexibility of being locked into a CAP vendor for a year regardless of the vendor?s adherence to quality and accurate timely delivery. Physicians should have the option to leave the CAP program if the selected CAP vendor leaves the program mid-year or fails to satisfy the physicians.

2. The integrity of the drugs is endangered. To ensure quality and product integrity, vendors should be prohibited from opening drug containers and physicians should be permitted to return damaged or suspicious drugs.

3. Will CAP vendors? formularies include all drugs?

4. CAP?s requirements for written prescriptions and patient-specific inventories create the potential for costly ?waste? from unused medications, not to mention delays, inconveniences, and burdensome claims for patients.

5. Participation in this CAP plan requires signed election forms that commit oncologists to order drugs via written prescriptions for each individual patient and submit Medicare claims within 14 days of drug administration with the prescription number for each drug administered.

These costs will just be added to the long list of ?uncompensated? costs of ordering, tracking, and filing CAP claims, pursuing appeals and sharing information with vendors to help them collect co-payments.

We do not have the administrative capabilities to satisfy these requirements.

It?s clear that the CAP plan will seriously impair our financial viability, as MMA has. Tomorrow?s physicians will choose wisely, and choose another specialty. Tomorrow?s patients will have little chance of skilled, convenient, cost-effective community-based cancer care.

Submitter : **Dr. Mohammed Ali** **Date: 04/25/2005**

Organization : **Cancer Health Treatment Centers**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

Submitter : Dr. Michele Reid **Date:** 04/25/2005

Organization : Detroit-Wayne County Community Mental Health Agenc

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I recommend including injectable psychotropic medications in the CAP program. The cost of such drugs has increased dramatically over the last 20 years and is posing an access problem for patients in Michigan. These drugs are needed and without appropriate access can reuslt in unecessary hospitalization. By allowing psychiatrists to particpate in this program access will be improved. Please note that such patients often get thier medications from Community Mental Health and the medication is given in the patients home versus the doctors office. Please be sure to allow the site of service to be in the community as well as the doctors office. I think this is a great policy and should definitely include psychotropic medications in the inital phase of the CAP program.

Submitter : Dr. Mohammed Ali **Date:** 04/25/2005

Organization : Cancer Health Treatment Centers

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-275-Attach-1.DOC

April 25, 2005

Centers for Medicare and Medicaid Services
Dept. of Health & Human Resources
ATTENTION: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: Comments put forth by the American Society of Clinical Oncology (ASCO) on the proposed rules governing the Competitive Acquisition Program (CAP) for drug administered in physician offices, which were published in the Federal Register March 4, 2005.

We the undernamed support and agree with the comments put forth by ASCO and request you provide full consideration to their comments made.

Sincerely,

Robert T. Woodburn, M.D.
Pimpa J. Tara, M.D.
Virginia Tan Tabib, M.D.
Cheryl Morgan-Ihrig, M.D.
M.Y. Ali, M.D.
J.P. Sanghvi, M.D.
B. Keralavarma, M.D.
Murugavel Muthusamy, M.D.
George Sloan, M.D.

Cancer Health Treatment Centers
8127 Merrillville Road
Merrillville, IN 46410

Submitter : **Ms. Joe Love** **Date: 04/25/2005**

Organization : **Missouri Cancer Associates**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

In reviewing re-imbursement for stand-alone centers, please keep in mind that hospitals must not be allowed to compromise services. Hospitals are being deeply affected by stand-alone centers skimming the cream of the payor crop.

Submitter :

Date: 04/25/2005

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I practice in an area where "snowbirds" often come for 4-8 months. They receive their LHRN analogues from me down here and with their local urologist at home "up north. How could this be addressed since the patient doesn't always know how long the will be at either place.

Submitter : Mrs. Mary Ferkaluk **Date:** 04/25/2005

Organization : Mrs. Mary Ferkaluk

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

In its implementation of the Medicare Modernization Act of 2003 (MMA), the Centers for Medicare and Medicaid Services (CMS) has sought to more adequately cover the labor, supply, pharmacy, and other costs incurred in the administration of cancer-fighting drugs. Among the steps taken is the adoption of G codes to cover drug administration services and the creation of a demonstration project for 2005 that provided additional reimbursement.

As a result, 2005 Medicare reimbursement for cancer care services is considerably higher than pre-MMA rates. However, total reimbursement will drop dramatically on January 1, 2006, when the demonstration project is scheduled to end and the drug administration transitional factor will be zeroed out.

It has been calculated that the impact of these changes will translate into a $940 underpayment for drug administration services per Medicare beneficiary. Put another way, 2006 Medicare reimbursement for patient care services will cover only an estimated 50.09% of drug administration costs.

This problem is a key factor in the implementation of the Competitive Acquisition Program (CAP) in 2006. Under CAP, middlemen vendors will furnish drugs to physicians who choose to give up the traditional buy-and-bill model and select the CAP model instead. The vendors will be responsible for billing Medicare for the drugs, and the physicians will receive reimbursement only for drug administration services.

CMS expects CAP to appeal to those physicians ?who do not want to be in the drug procurement and drug coinsurance collection business? [70 Fed. Reg. 10750]. Indeed, statements made by CMS and CAP?s Congressional authors all reinforce the notion that CAP is intended to be an option that physicians may choose to adopt in place of the current buy-and-bill model. According to the MMA Conference Report produced by Congress, ?Conferees intend this choice to be completely voluntary on behalf of the physicians? [H. R. Conf. Rep. No. 108-391, 108th Cong., 1st Sess. 593 (2003)].

And yet, it is possible that neither CMS nor Congress has recognized that the viability of these two choices turns on the adequacy of reimbursement for drug administration services. Unless changes are made, many oncologists will face a loss under the buy-and-bill model, a loss that will be even greater should they opt to participate in CAP. This is because the only reimbursement they will receive under CAP is payment for drug administration services ? which will fall well below the cost of providing drug administration services.

In light of the reimbursement shortfall that looms on January 1, 2006, many cancer care specialists will face a very different choice than the one that Congress intended: continue to offer cancer care services to seniors (under buy-and-bill or CAP) and incur a significant net loss?or discontinue offering chemotherapy services to Medicare beneficiaries altogether. Sadly, both approaches threaten the community cancer care services on which millions of Americans now depend.

Congress has clearly stated its intent that patient access to community cancer care must be preserved because it is the source of convenient, cost-effective care for more than 4-out-of-5 American cancer patients. If CMS intends to abide by this intent, it must take additional steps to align Medicare reimbursement with the cost of drug administration services.

Because the level of needed fee schedule restructuring is significant, CMS may be unable to solve this pending crisis before the 2006 Physician Fee Schedule must be published. As a result, I urge CMS to extend the quality demonstration while it works to match drug administration cost and payments. Otherwise, both the CAP and the ASP models will be doomed to failure and many Medicare cancer patients likely will be forced back to hospitals for chemotherapy.

Submitter : Dr. Virginia Tabib **Date:** 04/25/2005

Organization : Cancer Health Treatment Centers

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-279-Attach-1.DOC

April 25, 2005

Centers for Medicare and Medicaid Services
Dept. of Health & Human Resources
ATTENTION: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: Comments put forth by the American Society of Clinical Oncology (ASCO) on the proposed rules governing the Competitive Acquisition Program (CAP) for drug administered in physician offices, which were published in the Federal Register March 4, 2005.

We the undernamed support and agree with the comments put forth by ASCO and request you provide full consideration to their comments made.

Sincerely,

Robert T. Woodburn, M.D.
Pimpa J. Tara, M.D.
Virginia Tan Tabib, M.D.
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B. Keralavarma, M.D.
Murugavel Muthusamy, M.D.
George Sloan, M.D.

Cancer Health Treatment Centers
8127 Merrillville Road
Merrillville, IN 46410

Submitter : Miss. Nancy Crispi **Date: 04/25/2005**

Organization : Nassau Hematology Oncology, PC

Category : Congressional

Issue Areas/Comments

1-15

Overview of the CAP

CAP program will cause numerous problems for the patient, the provider and CMS. The following are only a few of the problems that will occur: Patient inconvenience with schedules and drug delivery,no emergency provisions, Quality control and lack of vendor responsibility, additional staff needed for patient inventories and the tracking of discontinued medications that have been delievered but were not administered due to a change in treatment. As this will be effective on January 1, 2006 we strongly urge CMS to take the time it needs to fully understand how CAP can best be structured to attain Congress' objectives and benefit physicians without compormising access to drug therapies and treatment. Further , to ensure an effective launch with adequate vendor and physician participation, CMS must delay the effective date of CAP to such a time.

Categories of Drugs to be Included under the CAP

Once CMS has decided what "phase-in" approach it will take, a second notice must be published in the Federal Register to allow for public comment before the proposal can be adopted as a final rule.

Competitive Acquisitions Areas

Once CMS has decided how to define a "competitive acquisition area," a second notice must be published in the Federal Register before the proposal can be adopted as a final rule.

Submitter : Dr. Cheryl Morgan-Ihrig **Date:** 04/25/2005

Organization : Cancer Health Treatment Centers

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-281-Attach-1.DOC

April 25, 2005

Centers for Medicare and Medicaid Services
Dept. of Health & Human Resources
ATTENTION: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: Comments put forth by the American Society of Clinical Oncology (ASCO) on the proposed rules governing the Competitive Acquisition Program (CAP) for drug administered in physician offices, which were published in the Federal Register March 4, 2005.

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B. Keralavarma, M.D.
Murugavel Muthusamy, M.D.
George Sloan, M.D.

Cancer Health Treatment Centers
8127 Merrillville Road
Merrillville, IN 46410

Submitter : Dr. Ernie Balcueva **Date:** 04/25/2005

Organization : Michigan Society of Hematology & Oncology

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-282-Attach-1.DOC

CMS-1325-P-282-Attach-2.DOC

MSHO

Michigan Society of Hematology and Oncology

Advocacy - Research - Education

15 April 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: FILE CODE CMS-1325-P
COMMENTS ON THE MEDICARE PROGRAM; COMPETITIVE ACQUISITION OF OUTPATIENT DRUGS AND BIOLOGICALS UNDER PART B

On behalf of our membership of 313 practicing oncologists in the state of Michigan, the Board of Directors of the Michigan Society of Hematology and Oncology (MSHO) would like to comment on the proposed rules as published in the March 4, 2005 Federal Register concerning the implementation of the Competitive Acquisition Program (CAP) with a target date of January, 2006.

Our State Society serves as the voice of 90% of Michigan's community oncologists who have several concerns with the regulations as proposed in the CAP document and with the possible impact these regulations will have on our patients and our practices. As requested in the Federal Register document, we have organized our comments to match the section captions in the document.

- **CATEGORIES OF DRUGS TO BE INCLUDED UNDER CAP**

As we understand this section of the document, CMS is looking for comments on how this program could either be phased in by specialty or drug or whether the program should address all drugs used in the physician setting all at once.

Oncology is the specialty using the most broad and all encompassing drugs covered under Part B. By starting with the largest specialty, CMS may be increasing the likelihood of failure. That is, Oncology brings a tremendous volume of claims into the processing system. If the systems are new and untried, the influx of heavy claim submission could create a backlog and delay reimbursement. In addition, by beginning with the largest specialty, the error rates, claim denials, vendor claims issues, and system problems will be magnified.

3630 ROCKINGHAM - ROYAL OAK, MI 48073
PHONE (248) 549-1440 - (800) 456-3413 - FAX (248) 549-1608 - WEB SITE: WWW.MSHO.ORG

Since CAP will be a totally untried and untested program and that any interruption of a patient's cancer treatment endangers their chance of survival, we suggest that the pilot program be initiated with a smaller specialty with less patient care impact. We realize that possible vendors may not bid on the lower volume drugs, but feel that they would also be better served to move into the arena on a gradual basis as opposed to holding large numbers of unpaid claims in their accounts receivable

▪ COMPETITIVE ACQUISITION AREAS

The MSHO members would like CMS to be very cautious in selecting large areas for a vendor in the CAP initiative. Our concern is that a vendor will bid for the program in multiple areas, complete an RFP that would indicate they were able to handle that geographic area and then be unable to actually fulfill their responsibility. We would hope that CMS will make a very direct effort in the selection process to ensure that the vendor is capable at the outset to meet their obligations as opposed to being in the process of trying to assemble the needed warehousing, staffing and communications networks they require. All should be in place at time of selection and CMS should only consider vendors with the network in place. At least two (2) vendors in each region should be selected to give practices the option to choose the vendor based upon service and vendor commitment.

▪ CLAIM PROCESSING OVERVIEW

The Federal Register publication indicates that CMS feels the requirements of claim processing would place no additional burden on a physician practice under CAP. ***We STRONGLY disagree with the idea that this will place no additional burden on a practice and offer these reasons.***

⇨ *Claims to include an "order/prescription number"*

When a patient is examined in an office and chemo therapy is indicated, the physician will be required to submit a request to the vendor for the applicable drugs. The vendor creates a unique identification number and assigns it to the drugs upon delivery. It is now the practice's responsibility to inventory the drugs, store them until the patient arrives, makes the notation as to the ID number assigned to the drugs, then to remove them from inventory once the patient is treated and notify the vendor. ***This would be a totally new task for the practice.***

⇨ *Inventory Management*

In the Federal Register document it states, "we do not believe that separate physical storage of CAP drugs is required. However, we are proposing that physicians participating in the CAP would be required to maintain a separate electronic or paper inventory for each CAP drug obtained." The document indicates that this would not be burdensome to the practice and additional reimbursement would not be made. Our members maintain that this will in fact increase our administrative burden. Currently, most Oncology practices use an inventory cabinet that stores the drugs in the appropriate manner, monitors the drugs in the cabinet, keeps a

minimal amount of inventory on hand, checks the expiration dates and, in many cases interfaces with their practice management system to track usage. ***In whatever form, a separate inventory, not only for a particular carrier but a specific patient, would be required and the matching of drug with the order number would have to be added to the tasks performed by our nursing staff. This would add not only tremendous staff tracking duties but also require many practices to increase the size of their inventory space. Individual patient drugs need to be maintained - a large practice effort is required.***

⇨ ***Ordering Process***

Within the Claim Processing Overview section is contained reference to the actual placement of an order by the physician to the vendor. This area glosses over a few items that need to be addressed. First of all, if the physician places an order and expects to receive only the drugs needed for a particular visit and the vendor ships the drugs for a full course of treatment, how will the physician practice be expected to maintain these drugs in inventory for that patient? The practice would then be compelled to maintain the individual patient's inventory adding significant burden to the office staff. This is not affecting a small number of patients, but every Medicare patient coming in for treatment. This is a significant amount of inventory to maintain. The patient's treatment may change, be discontinued or be delayed for any number of reasons and the drugs are the responsibility of the physician. ***We feel that the vendor must be advised to ship only the amount of drug requested for that patient by their physician.***

This reason then brings up another area of concern we have experienced with other insurance carrier MVI programs. That is, the vendor ships only a partial order and not the complete order. This could be an oversight by the shipment department, could be the result of a problem with the patient's secondary insurance or because of an outstanding patient balance. ***CMS must direct the vendor to not suspend a shipment or parts of a shipment due to billing problems or patient outstanding balance***. This is a major patient safety issue. In each of our practices we have had to deal with secondary insurance problems and patients without financial ability to cover their deductible and copays. It has been our belief that health care should not be denied these patients and we work with them to resolve the issue. We have grave concerns that a vendor will not be equipped to handle nor have the background to work with patient advocacy groups and pharmaceutical companies to secure assistance for these patients. The physician is compelled to treat the patient in a timely fashion and would assume additional responsibility and liability. Should the vendor be allowed to discontinue shipment of a patient's drugs, who will be responsible for telling the patient that they cannot continue with treatment? If the patient's health fails and a lawsuit ensues, who will be held responsible? ***CMS must address these issues of responsibility and liability prior to implementation.***

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be then coerced into handling billing issues on behalf of the vendor, again with no reimbursement for this effort.

⇨ ***Unused Drugs***

Chemotherapy drugs are hazardous materials and require special handling. Within the claim section is reference to the unused drugs. Although not much definition is offered, we would like to raise a few questions in this regard.

When a patient's treatment course is outlined, drugs are ordered from the vendor anticipating that the patient will be able to begin the treatment. In many instances, a patient will present to the office and their examination reveals other problems that would either require a change in their treatment plan or the postponement of the treatment. The proposal suggests that the vendor and physician *"reach an agreement"* on what to do. Any option here contains a *host of possible issues*. For example, if the vendor says to use the drugs for another patient, they would have to make sure that the ID number assigned to the drugs when shipped either is transferred to the other patient or that it is cancelled. ***In either case, that would require the vendor and physician systems be updated in the same manner.***

There are many reasons why drugs would have to be sent back to the vendor other than a change in treatment plan. For example, patients have come in for consultation, education and returned on another day, have the IV started and then decide against chemo therapy. Once the drugs are mixed, they cannot be used in any situation. The vendor cannot bill for drugs not dispensed, the physician followed protocol and the patient exercised their prerogative to forego treatment.

Another scenario to be considered is a patient that moves or transfer care from one physician to another during the course of treatment. One physician has the drugs to send back and the other must order them.

If the drugs are to be sent back to the vendor, who is responsible for that cost? Is it to be assumed that since the physician is returning the product that he/she would bear the cost? *We ask CMS to direct the vendor to outline their position on the return of product.* Many vendors have very definite rules for sending drugs back and these would have to be made known not only to CMS in the selection process but to the physician at the time of his/her consideration of participation.

CMS also needs to consider the cost of hazardous waste material. Currently vials, bags, syringes containing chemotherapy residue are disposed of according to State regulations. ***The vendor would need to be responsible for this process since the reimbursement for administration of the drugs is not sufficient and no additional administrative funds are being made available to the physician.***

Also to be considered is drug waste. ***Since the drugs being delivered to the practice are for specific patients, the use of multi-dose vials will no longer be an option. The use of single dose vials will increase the amount of drug being wasted.*** This will be a tremendous inefficiency and increase the cost rather than decrease the cost of the drug. Any attempt to re-use a vial would either constitute a patient safety issue or be fraudulent billing. Have the pharmaceutical companies been consulted on this issue?

⇨ ***Emergency Situations***

This section also assumes that the physician has an inventory from which to acquire drugs in an emergency situation. The reality is that with the implementation of CAP, a physician may not have an inventory at all. Physician practices rely on volume to help lower the purchase cost of drugs. CAP places all the buying power with the vendor leaving the physician to rely only on that particular source for drugs not only for Medicare patients but all patients treated in the practice. ***To assume that the physician has a personal inventory is an error and should be closely investigated. In addition, the outline of what would constitute an emergency is not adequate.*** This would also place additional burden on the practice should it occur. For example, if the patient does have a supply of a medication on hand and uses some of that stock for a patient, it may be possible for the drug to not be replaced. As stated earlier, in many cases a patient may require a change in medication that is only known when they present for treatment. There would be no way to have this information available prior to their visit and no vendor would be able to get drugs to the physician while the patient waited. The physician would place an order to the vendor indicating that the medication came from personal inventory. The vendor would ship the drug without the patient ID information to replace the drug. The chance of error in this area is great. If the vendor staff did not note that it was replacement drug, the patient has drug shipped that they already had administered. The physician cannot bill for the medication and has paid for the drug. ***We would like CMS to clearly define emergency situations in light of these protocol changes.***

⇨ ***Off Label Use***

Another area that we feel is not solidly defined is the use of FDA approved drugs in off label situations and clinical trials. Oncology treatments are constantly changing and the use of drugs for indications other than the initial release are quite frequent. Currently the Oncologist will work their State Society to gather information supporting the off label use of a product. This information is then sent to our Fiscal Intermediate (WPS for Michigan) and reviewed for approval/denial. The system is very flexible and allows the carrier to review data and make an informed decision. In these situations, the patient's best interest is always of the utmost importance. When the drugs are out of the physician's control, what happens in situations like this? Will the physician be dependent upon the vendor to get approval for off label use? Will the vendor not allow any off label use and restrict the physician's treatment of patients?

Although the drugs in clinical trial are available at no cost, there are ancillary drugs and supplies used in the trial. When a practice enrolls in the trial are the drugs sent to the practice or to the vendor? Who is tracking this part of the inventory? Will the vendor understand the billing nuances for the other medications?

In cases of clinical trials and off label use, the advancement of cancer treatment could be significantly slowed, subject patients to less beneficial treatment but also expose the physician to tremendous liability. ***CMS must firmly outline how off label use of drugs is to be handled and insure that clinical trials are not compromised.***

▪ DISPUTE RESOLUTION

The vendor will be able to report non-conforming physicians to CMS and possibly have the physician removed from the CAP initiative. ***This same prerogative is not offered the physician.***

Once the physician has decided to become a part of CAP, the only indication in the published guidelines for them to change vendors is if the vendor is removed from the program. ***There is no mention of the recourse a practice would have to not only leave the CAP program but to change vendors.*** If a vendor is placing too much burden on the administrative staff in a practice or if they are not adequately working with the patients in the collection of secondary carrier benefits, the physician must continue to order from that vendor for a year even though the relationship is not in anyone's best interest. ***We request CMS to allow physicians the option to change vendors within the year time frame if the initial distributor fails to meet the needs of the practice beyond quality and timely delivery. The way the vendor interacts with the patients should be considered an allowable means of ending the agreement.***

▪ CONTRACTING PROCESS-QUALITY AND PRODUCT INTEGRITY ASPECTS

The MSHO members would like CMS to ***hold the vendors to strict quality control mechanisms.*** This would include requiring vendors to not open or in anyway tamper with the drug containers, carry insurance to cover possible harm caused by their handling of the drugs, include contract language to hold the physician harmless if a lawsuit is initiated because of the possibility of compromised drugs or "gray market" drugs used in treatment and lastly, CMS should audit and enforce the quality standards.

▪ PHYSICIAN ELECTION PROCESS

In order for a physician to make a decision to participate in CAP or not, full and complete information should be made available to them.

This information would include:

- ✓ a complete price list so that they may compare their purchase cost against the amount submitted by the vendor as well as to the reimbursement from CMS on the drugs
- ✓ a detailing of the vendor's drug return policy
- ✓ a detailed explanation of what is expected of them in the submission of orders and ultimately claims
- ✓ claims resolution steps and the burden of the physician
- ✓ the vendor's policy for collecting secondary insurance copays and deductibles
- ✓ a certificate of insurance outlining the liability coverage of the vendor
- ✓ contract language that details the physicians liability
- ✓ a detailed explanation of the vendor's policy regarding direct patient billing
- ✓ certification that prescriptions will be filled according to the physician's orders
- ✓ details of the delivery schedules with an outline of what is to happen if deliveries are delayed for any reason
- ✓ regulations regarding leaving CAP
- ✓ inventory requirements and all the incentives being offered by pharmaceutical companies to the vendor that affects their marketing and product availability.

Based upon the amount of information being gathered and having to be reviewed, we would suggest that the enrollment process be given as much time as possible so that the physician is able to make an informed decision and arrange for the necessary software changes (if any).

As practicing Oncologists the MSHO members can appreciate the efforts of CMS to contain rising costs and not impact the care of cancer patients in the country. We would also like to express our strongest argument against the premise that these changes will not place any additional burden on the physician practice. ***Based upon the outlined needs and the volume of patients treated in Oncology practices, it would not be an exaggeration to state that 1-2 FTE's would be needed per practice to handle the additional duties being imposed. The small and rural practices will be the most severely impacted with these proposed regulations.*** It is not our intention to have to shift patient care to hospitals. Hospitals do not have the infrastructure to handle a large influx of chemo therapy patients. Patients will be required to wait for long periods of time, travel greater distances and loose the comfort of being treated by the same people on an ongoing basis. Our goal to keep the patient in the care of their community oncology practice where the patients come first and the quality of care is well proven and established. However, with the duties and obligations being made upon these practices by CAP, many will not be able to maintain office based treatment.

We also hope that CMS makes decisions with the quality of patient care uppermost in their minds and not just the bottom line.

Thank you for the opportunity for the MSHO membership to expresses their comments and opinions on the proposed regulations.

Thank you for your consideration,

Ernie Balcueva, M.D.
President
Michigan Society of Hematology and Oncology

MSHO

Michigan Society of Hematology and Oncology

Advocacy - Research - Education

15 April 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: FILE CODE CMS-1325-P
COMMENTS ON THE MEDICARE PROGRAM; COMPETITIVE ACQUISITION OF OUTPATIENT DRUGS AND BIOLOGICALS UNDER PART B

On behalf of our membership of 313 practicing oncologists in the state of Michigan, the Board of Directors of the Michigan Society of Hematology and Oncology (MSHO) would like to comment on the proposed rules as published in the March 4, 2005 Federal Register concerning the implementation of the Competitive Acquisition Program (CAP) with a target date of January, 2006.

Our State Society serves as the voice of 90% of Michigan's community oncologists who have several concerns with the regulations as proposed in the CAP document and with the possible impact these regulations will have on our patients and our practices. As requested in the Federal Register document, we have organized our comments to match the section captions in the document.

- **CATEGORIES OF DRUGS TO BE INCLUDED UNDER CAP**

As we understand this section of the document, CMS is looking for comments on how this program could either be phased in by specialty or drug or whether the program should address all drugs used in the physician setting all at once.

Oncology is the specialty using the most broad and all encompassing drugs covered under Part B. By starting with the largest specialty, CMS may be increasing the likelihood of failure. That is, Oncology brings a tremendous volume of claims into the processing system. If the systems are new and untried, the influx of heavy claim submission could create a backlog and delay reimbursement. In addition, by beginning with the largest specialty, the error rates, claim denials, vendor claims issues, and system problems will be magnified.

3630 ROCKINGHAM - ROYAL OAK, MI 48073
PHONE (248) 549-1440 - (800) 456-3413 - FAX (248) 549-1608 - WEB SITE: WWW.MSHO.ORG

Since CAP will be a totally untried and untested program and that any interruption of a patient's cancer treatment endangers their chance of survival, we suggest that the pilot program be initiated with a smaller specialty with less patient care impact. We realize that possible vendors may not bid on the lower volume drugs, but feel that they would also be better served to move into the arena on a gradual basis as opposed to holding large numbers of unpaid claims in their accounts receivable

▪ COMPETITIVE ACQUISITION AREAS

The MSHO members would like CMS to be very cautious in selecting large areas for a vendor in the CAP initiative. Our concern is that a vendor will bid for the program in multiple areas, complete an RFP that would indicate they were able to handle that geographic area and then be unable to actually fulfill their responsibility. We would hope that CMS will make a very direct effort in the selection process to ensure that the vendor is capable at the outset to meet their obligations as opposed to being in the process of trying to assemble the needed warehousing, staffing and communications networks they require. All should be in place at time of selection and CMS should only consider vendors with the network in place. At least two (2) vendors in each region should be selected to give practices the option to choose the vendor based upon service and vendor commitment.

▪ CLAIM PROCESSING OVERVIEW

The Federal Register publication indicates that CMS feels the requirements of claim processing would place no additional burden on a physician practice under CAP. ***We STRONGLY disagree with the idea that this will place no additional burden on a practice and offer these reasons.***

⇨ *Claims to include an "order/prescription number"*

When a patient is examined in an office and chemo therapy is indicated, the physician will be required to submit a request to the vendor for the applicable drugs. The vendor creates a unique identification number and assigns it to the drugs upon delivery. It is now the practice's responsibility to inventory the drugs, store them until the patient arrives, makes the notation as to the ID number assigned to the drugs, then to remove them from inventory once the patient is treated and notify the vendor. ***This would be a totally new task for the practice.***

⇨ *Inventory Management*

In the Federal Register document it states, "we do not believe that separate physical storage of CAP drugs is required. However, we are proposing that physicians participating in the CAP would be required to maintain a separate electronic or paper inventory for each CAP drug obtained." The document indicates that this would not be burdensome to the practice and additional reimbursement would not be made. Our members maintain that this will in fact increase our administrative burden. Currently, most Oncology practices use an inventory cabinet that stores the drugs in the appropriate manner, monitors the drugs in the cabinet, keeps a

minimal amount of inventory on hand, checks the expiration dates and, in many cases interfaces with their practice management system to track usage. ***In whatever form, a separate inventory, not only for a particular carrier but a specific patient, would be required and the matching of drug with the order number would have to be added to the tasks performed by our nursing staff. This would add not only tremendous staff tracking duties but also require many practices to increase the size of their inventory space. Individual patient drugs need to be maintained - a large practice effort is required.***

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Also to be considered is drug waste. ***Since the drugs being delivered to the practice are for specific patients, the use of multi-dose vials will no longer be an option. The use of single dose vials will increase the amount of drug being wasted.*** This will be a tremendous inefficiency and increase the cost rather than decrease the cost of the drug. Any attempt to re-use a vial would either constitute a patient safety issue or be fraudulent billing. Have the pharmaceutical companies been consulted on this issue?

⇨ ***Emergency Situations***

This section also assumes that the physician has an inventory from which to acquire drugs in an emergency situation. The reality is that with the implementation of CAP, a physician may not have an inventory at all. Physician practices rely on volume to help lower the purchase cost of drugs. CAP places all the buying power with the vendor leaving the physician to rely only on that particular source for drugs not only for Medicare patients but all patients treated in the practice. ***To assume that the physician has a personal inventory is an error and should be closely investigated. In addition, the outline of what would constitute an emergency is not adequate.*** This would also place additional burden on the practice should it occur. For example, if the patient does have a supply of a medication on hand and uses some of that stock for a patient, it may be possible for the drug to not be replaced. As stated earlier, in many cases a patient may require a change in medication that is only known when they present for treatment. There would be no way to have this information available prior to their visit and no vendor would be able to get drugs to the physician while the patient waited. The physician would place an order to the vendor indicating that the medication came from personal inventory. The vendor would ship the drug without the patient ID information to replace the drug. The chance of error in this area is great. If the vendor staff did not note that it was replacement drug, the patient has drug shipped that they already had administered. The physician cannot bill for the medication and has paid for the drug. ***We would like CMS to clearly define emergency situations in light of these protocol changes.***

⇨ ***Off Label Use***

Another area that we feel is not solidly defined is the use of FDA approved drugs in off label situations and clinical trials. Oncology treatments are constantly changing and the use of drugs for indications other than the initial release are quite frequent. Currently the Oncologist will work their State Society to gather information supporting the off label use of a product. This information is then sent to our Fiscal Intermediate (WPS for Michigan) and reviewed for approval/denial. The system is very flexible and allows the carrier to review data and make an informed decision. In these situations, the patient's best interest is always of the utmost importance. When the drugs are out of the physician's control, what happens in situations like this? Will the physician be dependent upon the vendor to get approval for off label use? Will the vendor not allow any off label use and restrict the physician's treatment of patients?

Although the drugs in clinical trial are available at no cost, there are ancillary drugs and supplies used in the trial. When a practice enrolls in the trial are the drugs sent to the practice or to the vendor? Who is tracking this part of the inventory? Will the vendor understand the billing nuances for the other medications?

In cases of clinical trials and off label use, the advancement of cancer treatment could be significantly slowed, subject patients to less beneficial treatment but also expose the physician to tremendous liability. ***CMS must firmly outline how off label use of drugs is to be handled and insure that clinical trials are not compromised.***

- **DISPUTE RESOLUTION**

The vendor will be able to report non-conforming physicians to CMS and possibly have the physician removed from the CAP initiative. ***This same prerogative is not offered the physician.***

Once the physician has decided to become a part of CAP, the only indication in the published guidelines for them to change vendors is if the vendor is removed from the program. ***There is no mention of the recourse a practice would have to not only leave the CAP program but to change vendors.*** If a vendor is placing too much burden on the administrative staff in a practice or if they are not adequately working with the patients in the collection of secondary carrier benefits, the physician must continue to order from that vendor for a year even though the relationship is not in anyone's best interest. ***We request CMS to allow physicians the option to change vendors within the year time frame if the initial distributor fails to meet the needs of the practice beyond quality and timely delivery. The way the vendor interacts with the patients should be considered an allowable means of ending the agreement.***

- **CONTRACTING PROCESS-QUALITY AND PRODUCT INTEGRITY ASPECTS**

The MSHO members would like CMS to ***hold the vendors to strict quality control mechanisms.*** This would include requiring vendors to not open or in anyway tamper with the drug containers, carry insurance to cover possible harm caused by their handling of the drugs, include contract language to hold the physician harmless if a lawsuit is initiated because of the possibility of compromised drugs or "gray market" drugs used in treatment and lastly, CMS should audit and enforce the quality standards.

▪ PHYSICIAN ELECTION PROCESS

In order for a physician to make a decision to participate in CAP or not, full and complete information should be made available to them.

This information would include:

- ✓ a complete price list so that they may compare their purchase cost against the amount submitted by the vendor as well as to the reimbursement from CMS on the drugs
- ✓ a detailing of the vendor's drug return policy
- ✓ a detailed explanation of what is expected of them in the submission of orders and ultimately claims
- ✓ claims resolution steps and the burden of the physician
- ✓ the vendor's policy for collecting secondary insurance copays and deductibles
- ✓ a certificate of insurance outlining the liability coverage of the vendor
- ✓ contract language that details the physicians liability
- ✓ a detailed explanation of the vendor's policy regarding direct patient billing
- ✓ certification that prescriptions will be filled according to the physician's orders
- ✓ details of the delivery schedules with an outline of what is to happen if deliveries are delayed for any reason
- ✓ regulations regarding leaving CAP
- ✓ inventory requirements and all the incentives being offered by pharmaceutical companies to the vendor that affects their marketing and product availability.

Based upon the amount of information being gathered and having to be reviewed, we would suggest that the enrollment process be given as much time as possible so that the physician is able to make an informed decision and arrange for the necessary software changes (if any).

As practicing Oncologists the MSHO members can appreciate the efforts of CMS to contain rising costs and not impact the care of cancer patients in the country. We would also like to express our strongest argument against the premise that these changes will not place any additional burden on the physician practice. ***Based upon the outlined needs and the volume of patients treated in Oncology practices, it would not be an exaggeration to state that 1-2 FTE's would be needed per practice to handle the additional duties being imposed. The small and rural practices will be the most severely impacted with these proposed regulations.*** It is not our intention to have to shift patient care to hospitals. Hospitals do not have the infrastructure to handle a large influx of chemo therapy patients. Patients will be required to wait for long periods of time, travel greater distances and loose the comfort of being treated by the same people on an ongoing basis. Our goal to keep the patient in the care of their community oncology practice where the patients come first and the quality of care is well proven and established. However, with the duties and obligations being made upon these practices by CAP, many will not be able to maintain office based treatment.

We also hope that CMS makes decisions with the quality of patient care uppermost in their minds and not just the bottom line.

Thank you for the opportunity for the MSHO membership to expresses their comments and opinions on the proposed regulations.

Thank you for your consideration,

Ernie Balcueva, M.D.
President
Michigan Society of Hematology and Oncology

Submitter : Dr. Jyotsna Sanghvi

Date: 04/25/2005

Organization : Cancer Health Treatment Centers

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-283-Attach-1.DOC

April 25, 2005

Centers for Medicare and Medicaid Services
Dept. of Health & Human Resources
ATTENTION: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: Comments put forth by the American Society of Clinical Oncology (ASCO) on the proposed rules governing the Competitive Acquisition Program (CAP) for drug administered in physician offices, which were published in the Federal Register March 4, 2005.

We the undernamed support and agree with the comments put forth by ASCO and request you provide full consideration to their comments made.

Sincerely,

Robert T. Woodburn, M.D.
Pimpa J. Tara, M.D.
Virginia Tan Tabib, M.D.
Cheryl Morgan-Ihrig, M.D.
M.Y. Ali, M.D.
J.P. Sanghvi, M.D.
B. Keralavarma, M.D.
Murugavel Muthusamy, M.D.
George Sloan, M.D.

Cancer Health Treatment Centers
8127 Merrillville Road
Merrillville, IN 46410

Submitter : **Dr. Belagopal Keralavarma** **Date: 04/25/2005**

Organization : **Cancer Health Treatment Centers**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-284-Attach-1.DOC

April 25, 2005

Centers for Medicare and Medicaid Services
Dept. of Health & Human Resources
ATTENTION: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

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B. Keralavarma, M.D.
Murugavel Muthusamy, M.D.
George Sloan, M.D.

Cancer Health Treatment Centers
8127 Merrillville Road
Merrillville, IN 46410

Submitter : Dr. George Sloan

Date: 04/25/2005

Organization : Cancer Health Treatment Centers

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-285-Attach-1.DOC

April 25, 2005

Centers for Medicare and Medicaid Services
Dept. of Health & Human Resources
ATTENTION: CMS-1325-P
P.O. Box 8010
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J.P. Sanghvi, M.D.
B. Keralavarma, M.D.
Murugavel Muthusamy, M.D.
George Sloan, M.D.

Cancer Health Treatment Centers
8127 Merrillville Road
Merrillville, IN 46410

Submitter : Dr. Bhanu Visvalingam **Date:** 04/25/2005

Organization : Coastal Cancer Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1325-P-286-Attach-1.DOC

April 25, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

Attn: CMS1325-P

Dear CMS,

I am a practicing community medical oncologist in the greater Myrtle Beach, South Carolina area. I appreciate the opportunity to comment on the Competitive Acquisition Program (CAP). I believe the Competitive Acquisition Program is inappropriate for patients in the community and does not serve their bests interests in terms of treatment for cancer.

Patients who are diagnosed with cancer requiring chemotherapy need to have flexibility with their treatment. Some patients need to have dosing adjustments made immediately. Some people have toxicities of treatment requiring immediate changes in the actual drugs that are administered for their specific malignant diagnoses. The CAP program does not allow for this flexibility of making very important treatment decisions for patients with life threatening cancer. Based on the proposed CAP rule, there would be delays in making therapeutic changes, so that the vendor would have to be contacted to have new drugs shipped to our office to provide appropriate treatment changes for their cancer therapy. This delay in therapy can be very critical in terms of taking care of patients with debilitating and life threatening cancer.

It appears that the billing system is cumbersome, as well as the ordering process. Furthermore, if a drug is supplied by a vendor and it is not administered to the patient the rule states "on the expected date of administration" the physician would notify the vendor and then "reach an agreement on how to handle the unused drug consistent with applicable state and federal law". This statement is unclear and there is no vehicle for handling waste disposal and cost of keeping the drugs viable, either in the doctor's office or potential reshipment back to the vendor. The problem of a supplied drug that is not used is going to be a significant issue throughout the country for practicing oncologists.

As far as the billing system, the rule states that vendors must work with physicians in terms of making sure claims are submitted timely and that there will be a vehicle for dealing with grievances, both from the physician, as well as the vendor. This is very unclear in a situation where chemotherapy drugs are very costly. We would be most concerned with vendors not providing appropriate drugs to the physician in a timely manner to best treat their patients. There is no coverage for indigent care, i.e. patients who do not have secondary co-pay insurance with the proposed CAP rule.

The rule does have a proposal for emergency situations; however, it states that "emergency orders received by 3:00 p.m. would need to be delivered the next day". Again, 3:00 p.m. western time or eastern time is obviously conflicting due to the three hour time differential from the east coast and west

coast. The majority of vendor suppliers may be on the east coast or potentially on the west coast. This would be a serious problem to patient care, especially those requiring emergent therapy.

Overall, I feel that the Competitive Acquisition Program is cumbersome, confusing, and inconvenient and will be a detriment to the quality of care that we have established throughout the country in community cancer care. Here in the Myrtle Beach area of South Carolina we have created an excellent community cancer care program to allow life saving treatment for patients debilitated with malignant diseases.

I thank you for the opportunity to comment on the proposed program. I do not recommend use of the Competitive Acquisition Program. There clearly needs to be more time spent on working out mechanisms for optimal drug delivery and treatment for patients requiring therapy for life threatening malignancies. Patients should not be penalized for changes in the drug delivery system under the proposed CAP rule provided by CMS.

Sincerely,

Bhanu Visvalingam, M.D.
Coastal Cancer Center
7 Medical Center Drive
Supply, NC 28462-3350
and
Coastal Cancer Center
8121 Rourk St
Myrtle Beach, SC 29572
843-692-5000
www.coastalcancercenter.com
BV/cjc

cc: Senator Richard Burr
Senator Elizabeth Dole
Representative Mike McIntyre
Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter : Dr. Murugavel Muthusamy **Date:** 04/25/2005

Organization : Cancer Health Treatment Centers

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-287-Attach-1.DOC

April 25, 2005

Centers for Medicare and Medicaid Services
Dept. of Health & Human Resources
ATTENTION: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: Comments put forth by the American Society of Clinical Oncology (ASCO) on the proposed rules governing the Competitive Acquisition Program (CAP) for drug administered in physician offices, which were published in the Federal Register March 4, 2005.

We the undernamed support and agree with the comments put forth by ASCO and request you provide full consideration to their comments made.

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B. Keralavarma, M.D.
Murugavel Muthusamy, M.D.
George Sloan, M.D.

Cancer Health Treatment Centers
8127 Merrillville Road
Merrillville, IN 46410

Submitter : Dr. Paul Sachs **Date:** 04/25/2005

Organization : Northwestern Human Services

Category : Other Health Care Professional

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

I am writing to recommend that mental health medications and therapies be included in Phase I of CAP.

1. Clinically and scientifically inclusion of mental health diagnoses makes sense. Neurological research shows more and more that the distinction between so-called 'mental' disorders and 'physical/medical' disorders is artificial at best. Individuals with 'mental' disorders are shown to have disrupted brain physiology and sometimes brain structural differences. Individuals with 'physical/medical' disorders evince emotional changes that are seen in changes in brain chemistry and metabolism. How can you sensibly include only 'physical/medical' medications and therapies for these disorders without including the same for 'mental' disorders?

2. Inclusion provides consumers easier access to care by simplifying the reimbursement process.
3. Inclusion provides another option for Medicare eligible consumers to obtain their needed medication.
4. Inclusion makes financial sense for society. By providing greater consumer access to the needed medications, CAP allows these individuals to attain greater emotional stability which will result in greater productivity for them and reduced drain on social services. Without providing such access CAP actually can increase to societal costs -- such individuals are less likely to obtain paying jobs and will result in greater drain rather than contribution to tax rolls.

Thank you for considering my comments.
Paul R. Sachs, Ph.D., MBA

Submitter : Dr. M. Michael Guffy **Date:** 04/25/2005

Organization : McFarland Clinic

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see Attachment

CMS-1325-P-289-Attach-1.DOC

McFarland Clinic PC

April 18, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

To Whom it may Concern:

We are a group of four Medical Oncologists practicing as part of a large multi-specialty clinic in central Iowa. We would like to comment on the proposed Medicare Program for the competitive acquisition of outpatient drugs and biologicals.

Comments on General Overview of CAP. File Code CMS-1325-P

As a general comment, we feel that this program will greatly add to the complexities of giving care to the Medicare population. We feel that it will add another layer of bureaucracy and in the end will ultimately increase the cost of medical care. It will further complicate the billing process and greatly confuse our patients. Lastly, and perhaps most importantly, we feel that this program will limit and restrict appropriate care for many of our patients.

Comments on Statutory Requirements Concerning Claims Processing

Many of our patients do not have co-insurance and are simply unable to afford the 20% of drug costs not covered by Medicare. Patients without co-insurance are frequently those patients who are least able to cover these costs on their own. In the past, we have been able to discuss these issues with our patients face to face and frequently made the decision to proceed with treatment knowing full well that we would not be able to collect the 20% co-payment. We did this because our principle mission has been to provide quality care to the public that we serve. Under the new CAP Program the vendors will now be responsible for collecting any applicable deductibles and co-payments. It is doubtful that vendors will be willing to make the same considerations with our patients that we have done in the past. The ultimate result will be that many deserving patients will go without appropriate care. This is a point that we cannot over emphasize. We feel that this program as implemented will restrict medical care.

As an example, we recently saw a patient in our practice with ovarian cancer. This woman required a complex chemotherapy program including Carboplatin and Paclitaxel to be cured of her disease. Unfortunately this women does not have co-insurance and simply cannot afford to pay the 20% co-pay on the cost of these medications. Despite this, we felt obligated to proceed with life saving therapy. By doing so we understood that we would be assuming some of the financial burden of her care. Without doubt however, this is a practice that "big business vendors" will not tolerate. As the current system is designed, we feel that this woman will be denied life saving therapy.

The current third party payment system already generates a medical bill that is difficult to decipher for even our most sophisticated patients. They receive bills for physician services, drug administration and drug costs from the physicians office. Factor into this deductibles and co-payments and the system becomes extremely confusing and frightening to the public. Under the CAP Program, yet another third party is added. The inevitable result will be to further complicate an already nightmarish program.

The practice of oncology is rapidly changing. New drugs for the treatment of cancer are rapidly becoming available and just as importantly, published studies expand the usefulness of drugs beyond their initial indication. The FDA may approve the use of a drug for one type of cancer but shortly thereafter, additional studies indicate that this drug is also useful in other forms of cancer. Currently, if we feel that a patient should receive a chemotherapy agent that is not approved for that indication there are mechanisms whereby that patient can still obtain this potentially life saving therapy. Initially, we can contact our local carrier and supply supportive literature to justify the drugs use in that setting. If however, our carrier still denies coverage, the majority of pharmaceutical companies will agree to replace drug that is used in that patient. This allows us to give what we feel is the best treatment and yet not shoulder the full burden of the cost if this medication. We do not see how this system or a similar system will work under the proposed CAP Program. What lines of communication between provider, vendor, pharmaceutical industry and local carrier are being established to facilitate, in a timely fashion, the use of drugs for indications not yet approved by the FDA?

Comments on Administrative Burden on Physicians

While the proposed CAP Program relieves physicians of collecting co-insurance for CAP drugs, the physician must comply with other administrative requirements. Physicians must maintain a separate electronic or paper inventory for each CAP drug obtained. Physicians would be required to submit claims to the local Medicare carrier when drugs are administered. When drugs are not administered, we will need to notify the vendor and rather than allowing us to use drugs at a later time it is our understanding that the proposed rules state that the vendor and physician must somehow reach an agreement on how to handle the unused drug. This is a daily event in our practice. Despite all this physicians are not entitled to any reimbursement for the administrative costs accrued as a result of participating in CAP! We submit that there are very real administrative costs to drug procurement and storage. It is astounding that the proposed system fails to make this recognition and yet still asks physicians to participate.

Under the current system, we have one inventory of drugs in our office. We draw from this inventory for all of our patients whether they have Medicare or other private insurance. The proposed CAP system will require that we have separate inventory for Medicare patients. The nightmare that this creates for us cannot be over emphasized.

It is obvious to us in reviewing the proposed CAP Program that the formulators of this program made little effort to understand or to take into account the complexities of oncologic care from the physicians perspective. We would urge that prior to the hasty implementation of such a program appropriate studies be done which fully explore and delineate its consequences.

Sincerely,

Michael Guffy, M.D.

Joseph Merchant, M.D

Larry Otteman, M.D.

Bassim Kobrossy, M.D.

MG:law

Submitter : **Marcia Garatt** **Date: 04/25/2005**

Organization : **Marcia Garatt**

Category : **Individual**

Issue Areas/Comments

1-15

Overview of the CAP

"Categories" of Part B drugs: as each individual has different biochemistry and metabolizes drugs differently and with different side effect profiles, I would hope that included in "categories", especially mental health drugs, would include all mental health drugs.

Categories of Drugs to be Included under the CAP

Please include in the final rule, excluding from CAP any drugs that are likely to cause patient access problems, specifically mental health drugs, including long-acting injectable antipsychotics.

Submitter : **Mrs. Susan Shafer** **Date: 04/25/2005**

Organization : **Thomas Peacock MD**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

The new CAP program will present a large problem to oncologists and in tern to the patients needing care. There is no was possible for a small office such as ours (1 doc 4 employees) to be able to track the CAP drugs as required as well as our private insurance patients drugs. We have no room to store more than 2 days worth of drugs and only 1 billing person who does all the billing making the 2 week reporting issue impossible. Further more down the line when the new drug vendors do not get the 20% copay from patients how will that be handled? Again we have a radically new process being put into use with little or no lead in time for everyone to learn how to use the new system.

Submitter : Dr. Harvey Neiman **Date:** 04/25/2005

Organization : American College of Radiology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-292-Attach-1.PDF

April 25, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850
File Code: CMS-1325-P

Re: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Proposed Rule

Dear Administrator McClellan:

The American College of Radiology (ACR), representing over 32,000 physicians specializing in radiology, radiation oncology, interventional radiology and nuclear medicine, would like to thank the Centers for Medicare and Medicaid Services (CMS) for this opportunity to provide comments on the proposed rule to implement the Competitive Acquisition Program (CAP) for outpatient drugs and biologicals covered under Medicare Part B (70 Fed. Reg. 10746, March 4, 2005). Our comments will focus on the section of the proposed rule that addresses "Categories of Drugs to be Included under the CAP" and the potential impact of this section on contrast agents, the drugs utilized by radiologists for medical imaging purposes.

Background

Section 303 (d) of the Medicare Modernization Act amends Title XVIII of the Act by adding a new section 1847B that requires the implementation of a competitive acquisition program (CAP) for Medicare Part B drugs and biologicals not paid on a cost or prospective payment system basis. Beginning with drugs administered on or after January 1, 2006, physicians will be given a choice between:

1. buying and billing these drugs under the average sales price (ASP) system, or
2. obtaining these drugs from vendors selected in a competitive bidding process.

As described by CMS in the proposed rule, the CAP may provide opportunities for Federal savings to the extent that aggregate bid prices are less than 106 percent of ASP. In addition, the CAP is designed to reduce the financial burden on physicians associated with employing working capital and bearing financial risk in the event of non-payment for drugs. The CAP also eliminates the need for physicians to collect coinsurance on CAP drugs from Medicare beneficiaries.

Categories of Drugs to be Included under the CAP

Section 1847B(a)(1)(B) of the Social Security Act (SSA) gives CMS the authority to phase-in categories of Part B drugs that would be offered under CAP. In the proposed rule, CMS identifies three major

options for the types of Part B drugs that would be included in the CAP program for its initial implementation for 2006. CMS does not propose a specific option for 2006, but rather seeks comment on the three options listed below:

1. All Part B drugs delivered "incident to" a physician's service;
2. Drugs used by a single physician specialty: oncology; or
3. Begin with specialties that use fewer Part B-covered drugs.

The ACR would like to comment on these options in the context of contrast agents, the drugs utilized by radiologists for medical imaging purposes. Millions of radiological examinations assisted by intravascular contrast agents are conducted each year in North America. In order to reduce the risk of adverse reactions and greater discomfort to patients, radiologists often utilize one type of agent in particular, low osmolar contrast medium (LOCM), to perform imaging services. As a result, the acquisition and payment process for LOCM, and other contrast agents, is of great interest to radiologists. Contrast agents fall into a special category of drugs and are used only in diagnostic imaging tests like x-ray, CT, MRI and echocardiography.

The ACR believes it may be premature to include contrast agents in the initial implementation of the competitive acquisition in 2006 for the following reasons:

1. The current ASP payment methodology for LOCM recently went into effect on April 1, 2005. Since that time, the Healthcare Common Procedure Coding System (HCPCS) codes for contrast agents have been significantly changed by the CMS HCPCS workgroup, and additional coding changes are scheduled for implementation on July 1, 2005. Prior to April 1, 2005, LOCM was reported with HCPCS Level II "A" codes: A4644-A4646. These codes have been replaced with seven new HCPCS Level II "Q" codes: Q9945-Q9951 for all Medicare patients except in the hospital outpatient setting. In addition, the ACR was pleased to work with CMS on expanding national coverage for LOCM to all Medicare beneficiaries. This decision resulted in many changes including the establishment of contrast agents under ASP. Since there have been many recent changes in coverage and reimbursement for LOCM under Medicare, the ACR recommends that CMS focus its attention on the implementation of the current ASP system for reimbursement of contrast agents, and monitor the progress of this system before including contrast agents in the CAP.

2. At present, most drugs like LOCM, high osmolar contrast medium (HOCM), magnetic resonance (MR) contrast agents, and echocardiography contrast agents are purchased through a large consortium of contrast vendors allowing physicians the freedom to choose specific contrast agents based on the needs of their patients. Under the CAP, CMS proposes that vendors will not be required to provide every National Drug Code associated with a HCPCS code. However, they also propose that vendors will be required to provide potential physician participants in the CAP the specific NDCs within each HCPCS code that they will be able to provide to the physician. We acknowledge that physicians will have a choice between buying and billing contrast agents under the average sales price (ASP) system or under the CAP. Nonetheless, the ACR is concerned that the ability of vendors to restrict the availability of these agents under the CAP will not be well understood and could leave those physicians who elect the CAP without access to the contrast

agent that the physicians ordinarily would have selected, based on the unique circumstances of individual patients.

3. For the payment of a new drug or biological under the CAP, CMS proposes to apply the payment amount established under the ASP methodology until the next annual update of the payment amounts established under the CAP. Since contrast agents are constantly advancing and changing, new contrast agents may not be readily available if there are any administrative delays in the creation of new HCPCS codes under the CAP process.

The ACR appreciates the opportunity to comment on the proposed rule. We will continue to follow this issue; and, we look forward to continued dialogues with CMS officials. Should you have any questions on the items addressed in this comment letter, or with respect to radiology and radiation oncology, please contact Carisia Switala at the ACR. Carisia may be reached at 1-800-227-5463 ext. 4587 or via email at CarisiaS@acr.org. Also, should CMS decide to proceed and include contrast agents under CAP, regardless of the above comments, we respectfully request that CMS discuss this with us before implementing such a change.

Respectfully Submitted,

[Endorsed copy to follow]

Harvey L. Neiman, MD, FACR
Executive Director

cc: John A. Patti, MD, FACR, Chair, ACR Commission on Economics
Arthur Segal, MD, FACR, Chair, ACR Committee on Drugs and Contrast Media
Pamela J. Kassing, ACR
Rachel S. Kramer, ACR
Margaret Wyatt, ACR

Submitter : Dr. Blaine Shaffer **Date: 04/25/2005**

Organization : Nebraska Psychiatric Society

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-293-Attach-1.DOC

NEBRASKA PSYCHIATRIC SOCIETY
A District Branch of the American Psychiatric Association
988470 Nebraska Medical Center
Omaha, NE 69198-8470

April 20, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Part B Competitive Acquisition Program, Categories of Drugs to be Included under CAP

Dear Dr. McClellan:

I am writing in strong support of the proposed rule recently issued by the Centers for Medicare and Medicaid Services (CMS) that addresses implementation of the Competitive Acquisition Program (CAP). This program has tremendous potential to benefit individuals with severe and persistent mental illnesses for whom injectable medications can help maintain adherence to drug regimens, treatment that is life-saving and essential to successful rehabilitation outcomes. We urge that injectable antipsychotic medications be included in the initial phase of CAP implementation.

Advantages of Injectable Psychiatric Medications

In 2003, the final report of the President's New Freedom Commission on mental health declared that recovery – helping individuals overcome the disabling aspects of mental illnesses – is the overarching goal of the U.S. mental health system. Addressing the means for attaining this goal, the report stated, " To achieve the promise of community living for everyone, new service delivery patterns and incentives must ensure that every American has easy and continuous access to the most current treatments and best support services." In implementing the CAP program, CMS has an opportunity to make a significant contribution to fulfilling the goals of the federal New Freedom Initiative by facilitating patient access to important psychiatric medications.

Patient noncompliance with psychotropic medication regimens is similar to that for patients who take medications for somatic illnesses. A review of the literature has found that most patients probably only take 33 – 94 percent of their prescribed drugs, with the median being about 50 percent for long-term therapy, while a sizeable percentage are wholly noncompliant.[a] For people with schizophrenia and severe mood disorders, noncompliance with medications often results in the relapse of acute symptoms, frequently resulting in negative outcomes such as rehospitalization, loss of employment/housing, and suicide. These negative consequences for the patient are compounded by a parallel negative impact on the service delivery system: costs escalate as outpatient treatment is stymied, the use of emergency facilities increases, and hospital stays are more frequent and longer.

The use of injectable antipsychotics has been recognized as an important, evidence-based practice that addresses the noncompliance of issue of many with schizophrenia. In addition, a new type of psychotropic medications show tremendous promise in addressing the issue of partial compliance among people with mental illnesses. These new medications are injectable, but do not have the side effect profile of older injectable depot psychotropics that consumers found objectionable, including lingering pain after the injection, sedation, and other effects. While a number of the new injectable medications are currently in development (including an antidepressant), one antipsychotic, an injectable form of risperidone, has been employed successfully in community-based settings for about a year, and it has shown great promise in treating schizophrenia.

The Schizophrenia Patient Outcomes Research Team (PORT) treatment recommendations, considered one of the most important practice guidelines for the treatment of schizophrenia, find that the older injectables are an important therapy for schizophrenia, stating that depot injectables should be "strongly considered for persons who have difficulty complying with oral medication..." The emerging evidence for the use of risperidone long-acting injection seems to indicate that the new injectable antipsychotics may offer significant clinical advantages to the older depot injectables, in addition to addressing the issue of noncompliance. Compliance is a significant issue in the treatment of schizophrenia, with 50 – 70 percent of all patients being only partially compliant in the first two years of treatment. A survey of studies found that noncompliance was associated with a risk of relapse that is 3.7 times greater than that for compliant patients.

Studies have found that use of long-acting injectable risperidone is associated with fewer and shorter hospitalizations[b] and improved functioning and quality of life.[c] Given the promise of these new injectable medications to improve outcomes for patients and reduce healthcare costs, and the recognition of the

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[a] Morris LS, Schulz RM. Patient compliance—an overview. J Clin Pharm Ther 1992, 17:283-95.

[b] Leal A, Rosillon D, Mehnert A et al. Healthcare resource utilization during 1-year treatment with long-acting injectable risperidone, Pharmacoepid Drug Safety, 2004, 13: 811-816.

[c] Nasrallah HA, Duchesne I, Mehnert A, et al. Health-related quality of life in patients with schizophrenia during treatment with long-acting injectable risperidone. J Clin Psychiatry 2004, 65:531-536.

use of injectable depot medications as an evidence-based practice, we believe that CMS should make consumer access to injectable antipsychotic

medications an urgent priority. As other new injectable psychotropics become available, we suggest that CMS prioritize efforts to enhance consumer access to these drugs.

Current Obstacles Faced by Providers Using Injectable Psychiatric Medications

Unfortunately, community mental health centers (CMHCs) and other multi-service community providers, which serve a large number of people with severe mental illnesses that are eligible for both Medicaid and Medicare, face serious obstacles in providing injectable medications. As safety-net providers, CMHCs are very often heavily burdened treatment settings that lack sophisticated information technology and a sufficient level of administrative staffing. For example, to provide the new injectable antipsychotic risperidone to patients, CMHCs must first purchase the medication, and then seek reimbursement from both Medicare (which makes only partial payment for mental health drugs) and Medicaid. Providers then bear the administrative burden of tracking the claims and the financial risk of receiving incomplete payment from one or both payers. This burden has become an impediment to expanding access to this medication to the full range of patients who could benefit from it. In some cases, CMHCs will only provide the medication to patients that are solely Medicaid beneficiaries. When injectable antipsychotics are included in the Medicare CAP program, this substantial impediment will be removed, as providers would have the option to obtain the medications from a drug vendor that will handle reimbursement from Medicare. Helping providers expand access to this medication will bring great benefit to our patients with schizophrenia.

From a brief review of the proposed rule, it appears that CMS may view oncology medications as the primary medication category to be included in the initial phase of CAP. CAP also has the potential to bring new psychiatric therapies into wider use and to significantly improve the quality of care for some of the most vulnerable people in our society – helping to "achieve the promise" of the New Freedom Initiative for people with psychiatric disabilities. We urge you to

include coverage of antipsychotic injectable medications in the drug categories that compose the initial phase of CAP implementation.

Sincerely,

Lawrence B. Shaffer, MD
President
Nebraska Psychiatric Society

Submitter : Mr. Dave Dillahunt **Date:** 04/25/2005

Organization : OH\WV Hematology Oncology Society

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-294-Attach-1.PDF

Hematology Oncology Society

OH\WV Hematology Oncology Society
3401 Mill Run Drive●Hilliard OH 43026
614.527.6751●614.527.7979(Fax)
www.ohwv.org

April 25, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: **CMS-1325-P**
P.O. Box 8010
Baltimore, MD 21244-8010

Dear CMS:

These comments are submitted by the Ohio\West Virginia Hematology Oncology Society in response to the proposed rules governing the Competitive Acquisition Program (CAP) for drugs administered in physician offices, which were published in the Federal Register on March 4, 2005. The Society is a non-profit organization representing over 190 medical oncologists in the states of Ohio and West Virginia. We are submitting comments regarding CMS' proposed rule on the Competitive Acquisition Program for drugs. In general, the proposed regulation will create a significant non-reimbursed administrative and economic burden on physician offices and will create additional burdens for patients and could deny patients access to vital drugs to help treat their serious diseases. Specific comments are below.

Payment for Administrative Costs

In the proposed rule, there is no provision for compensating physicians for the administrative burdens of participating in CAP because (in CMS' view) there will be negligible clerical and inventory resources associated with participation in the CAP as opposed to the current ASP reimbursement system. The Society disagrees with this conclusion and suggests that a separate payment be established. At each step in the process of procuring, using, and billing for drugs under the CAP, the administrative work is greater than under the reimbursement system.

Under CAP practices would be responsible for providing the following paperwork to the CAP vendor for every drug/treatment order:

- Date of order
- Beneficiary name
- Physician name, practice location, group practice information (if applicable), PIN and UPIN
- Drug name
- Strength
- Quantity ordered
- Dose
- Frequency/instructions
- Anticipated date of administration
- Beneficiary Medicare information/Health insurance (HIC) number
- Supplementary Insurance info (if applicable)

Hematology Oncology Society

Medicaid info (if applicable)
Shipping address
Additional Patient Info: date of birth, allergies, Ht/Wt/ICD-9, etc.

Additionally, practices would be required to:
Maintain a separate electronic or written inventory of each CAP drug
Notify vendor when a drug is not administered on the expected date
Include on bill for drug administration:
Drug administration code
HCPCS for CAP drug
Specific drug prescription number for each CAP drug (the prescription number will change with each shipment)

The costs of ordering drugs under the CAP would be significantly greater than under the reimbursement system. Practices that elect to participate in the CAP program will need to create several inventories and inventory systems, one for each Medicare patient drug and one for non-Medicare patients. This will also impede the usefulness of current electronic ordering inventory management systems. The identity of each drug received from the CAP vendor would need to be entered into a record together with the identifying number furnished by the CAP, and a further entry into the inventory record would be required when the drug was administered. Physicians currently do not maintain any similar inventory records, and the additional work involved would be substantial.

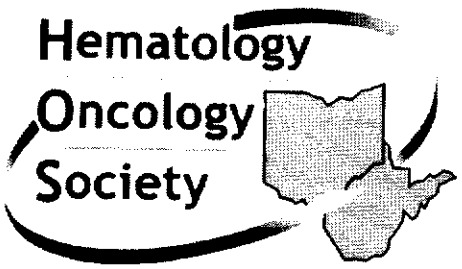
In addition to filing all claims with Medicare for the drug's administration, physicians will now have to include a new prescription number with the claim. Currently, most billing programs are not designed to accommodate this number. In order to incorporate the required prescription number, physicians will have to incur the cost of purchasing new software or editing their existing program.

These new requirements will certainly increase the cost of health care due to the inefficiencies of separate inventory systems, re-engineering current inventory systems, increased paperwork and the associated staff time. In sum, there is no basis for CMS's conclusion that no extra administrative costs are incurred by physicians participating in the CAP. We recommend that a reasonable payment be established that would fully cover the extra costs involved. The payment amount could be paid with respect to each drug administered.

Use of Non-Vendor Drugs

The proposed rule allows, under certain circumstances, the physician to use drugs from his\her own inventory to be replaced by the vendor; however the physician must be able to demonstrate all of the following:

The drugs are required immediately;
The physician could not have anticipated the need for the drug (Then why would the physician have it in inventory?);
The vendor could not deliver the drugs in a timely manner (what is considered a timely manner?);
And the drugs were administered in an emergency situation.



Who will determine whether the criteria have been met - the physician, vendor, or CMS? At what point will it have to be proven? Will the physician be required to prove the need before administering the drug to a patient, or before getting paid for having to use his/her own drug supply? If the vendor claims that it was not an emergency situation, to whom can the physician appeal that decision? Won't this uncertainty place a chilling effect on physicians using their own drugs for Medicare patients?

There are simply too many unanswered issues on this provision that can have a negative impact on patient care. Physicians would have to think very carefully before maintaining their own inventory of drugs under this scenario.

CAP Bidding Process – Evaluation and Selection

Use of New Drugs

The proposal indicates that adjustments to the vendors' payment schedule will be made annually. This proposal implies that a CAP vendor would not be obligated to furnish newly approved drugs to patients for a period of some months.

It is essential that all newly approved Medicare-covered drugs be immediately available to Medicare patients. This availability is especially important in the case of new cancer drugs, which may extend patients' lives. CMS should coordinate with the FDA on new drug approvals and immediately revise the vendor payment schedule to include new drugs. Alternatively, CMS should clarify in the regulations that physicians who have agreed to obtain their drugs from a CAP vendor are nevertheless free to buy and seek reimbursement for new drugs until they are available from the vendor.

Off-label Drug Use

Physicians now have the ability to take the financial risk of using drugs off-label when they feel that drug is the most appropriate therapy for the patient and appeal the denial of the use of that drug for off label use to the local carrier. How would the proposed rule affect the ability of physicians to "go to bat" for their patients on an off label use?

Under the proposed rule if a claim is denied for medical necessity, only the physician has appeal rights. If a physician orders a drug that is not consistent with the LCD, does the CAP vendor have the right to refuse shipment of that drug? If the drug is shipped and administered and subsequently denied by Medicare what is the physician's responsibility in assisting the vendor to receive payment on the drug?

Non-payment of Patient Coinsurance

Presently, physicians have the flexibility to offer patients' payment plans when they can't pay their coinsurance in full. Under the CAP, if a Medicare patient can't pay their coinsurance do the vendors have the right to deny shipment of the patient's drugs in the future? If so, when and how will the physician and patient be informed? Where will the patient turn to receive treatment? Who will be liable for withholding treatment for the patient?

Hematology Oncology Society

The regulations should state that the vendor may not refuse to fill a properly completed physician's order for any reason whatever (e.g., the patient involved has not paid coinsurance owed to the vendor for a previous order or the Medicare carrier has denied coverage of a similar previous order).

Patient Assistance Programs

Physicians currently work with drug manufacturers to obtain drugs for those patients with financial needs. Now that the physicians are taken out of drug procurement under this program, will vendors participate in patient assistance and drug replacement programs? Will they assist patients with pharmaceutical company drug assistance programs?

Drug Delivery

Vendors would be required to supply a drug for each of the HCPCS J-codes identified, but in the case of multiple-source drugs, they would only be required to supply one manufacturer's version. Physicians may be forced to change a patient's therapy based on drugs available by the vendor. The vendor will have authority to impose substitution and dosing restrictions. Patients may be forced to switch therapies and strengths. Vendors may not offer access to all current therapies and patients may be forced to switch their drug or dose.

If vendors implement formularies in order to receive discounted prices from manufacturers, how can the formulary be changed? If a particular drug brand (or formulation of drug) necessary for an individual is not available through the vendor due to formulary considerations, what is the process to obtain the necessary drug for the patient? Who will be responsible for the cost of that drug?

Occasionally there are shortages in a particular drug. If such a drug is on a formulary of the CAP vendor and out of inventory, where does the patient go for the drug? Or if a patient needs a specific non-formulary drug due to allergies?

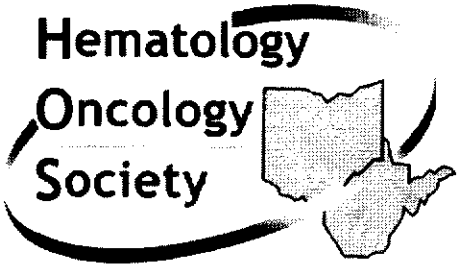
Contracting Process – Quality and Product Integrity

Disposition of Unused Drug

First, the proposal on the disposition of unused drugs appears to contemplate that the physician can predict the exact date on which drugs will be administered to the patient. A patient's schedule for cancer chemotherapy is subject to change based on the patient's condition, and it should not be assumed, as the proposal does, that a failure to administer a particular drug on the date predicted in advance means that the drug will go unused.

Second, it would be much more practical for the vendor to track the use of drug than the physician. The proposal contemplates that physicians would develop a new system of inventory records for each drug.

Third, the process for disposing of unused drug should be clarified. The proposal implies that the disposition of unused drug is at the discretion of the vendor and that, if the vendor cannot develop a solution that is consistent with the state and federal law, the vendor incurs the financial loss. While we understand that CMS cannot resolve all of the state law questions that may be involved, it would be useful if CMS clarified the principles involved. In particular:



- Is the vendor allowed to do anything with the unused drug that is permissible under state law or are there any restrictions under the CAP or other federal law that would apply?
- To what extent is the physician required to cooperate with the vendor with respect to unused drug? For example, if the vendor concludes that it can legally take the unused drug back from the physician, is the physician required to send the drug back? If so, the physician should be permitted to charge the vendor a fee for the service of returning the drug; is such a charge allowed?
- Is the physician required to mitigate the vendor's loss by offering to administer the drug to a different Medicare patient?

Other questions involve whether drugs are delivered in the vial size/sizes that most closely relate to the dose or will drugs be delivered pre-mixed for the patient? Who will be responsible that the correctly labeled drug and dose is provided, and properly shipped to the physician's office (e.g., some drugs require refrigeration, whereas others are kept at room temperature)?

Finally, there are significant expenses associated with the disposal of drug waste. Who is responsible for the cost associated with that waste disposal? Since these drugs are not the physician's anymore, the CAP vendor should be responsible for the cost of drug waste disposal.

Product Integrity

The statute authorizes CMS to impose product integrity safeguards. An issue that the regulations should deal with expressly is the authority of vendors to open drug containers. The Society is concerned, for example, that if a vendor believes that a particular patient's order does not require a full container of drug, the vendor, acting as a pharmacy, may open a container and dispense only the portion that the vendor believes is necessary by transferring a portion of the drug to another container for shipment to the ordering physician.

Any compromise of package integrity in this manner would be unacceptable. The regulations should clearly require vendors to ship products to physicians in containers that are unopened and otherwise in the same condition as received from the drugs' manufacturers.

Return of Damaged or Suspicious Drugs

The rules should permit physicians to return to the vendor, without penalty, any drug that arrives in damaged condition or whose integrity the physician reasonably believes may have been compromised. The vendor should not be permitted to require the physician to seek a remedy from the company that delivered the product.

Vendors Should be Required to Carry Substantial Liability Insurance

The proposed financial standards should include a requirement that vendors carry substantial liability insurance. In the event that vendor error cause harm to patients, their liability for damages could be substantial, and the proposed regulations for financial adequacy to conduct a drug distribution business may not be adequate to ensure their ability to pay damages.

Hematology Oncology Society

CMS Should Audit Compliance with and Enforce the Standards

The only review and enforcement mechanism in the proposed regulations regarding quality and other standards appears to be the vendor's certifications that it is in compliance. We believe that CMS should take a more affirmative role in determining vendor compliance by, for example, inspecting vendor facilities, monitoring complaints, auditing vendor compliance with time schedules in the regulations, and so forth.

Miscellaneous Issues

When ordering drugs from the vendor, providers must submit a written order for patients, which will include a treatment and delivery schedule. This structure does not account for individuals who may obtain the drug from multiple locations, such as "snowbirds", thus creating additional paperwork and possible confusion among providers.

This would also require patients to make two separate visits to the physician's office for treatment. The first visit would be to see the physician for evaluation and management, and lab monitoring. Then a second visit on another date to receive the therapy – since the treatment needs to be calculated based on the individual patient's size and blood counts, plus adjustments for any adverse side effects. This would create an additional burden on patients, who in most situations receive treatment on the same day as the physician evaluation.

As you can see, there are numerous issues that have not been assessed by the proposed rule. Physicians who elect to participate in the CAP program will face significant administrative burdens and increased costs. At a time when reimbursement rates for oncology services have been severely cut and the possibility of another across-the-board cut for physician services looming, these additional burdens under the proposed rule will further strain the ability to maintain an oncology practice.

The creation of this program will also increase health care costs, by simply adding additional bureaucratic requirements for the treatment of Medicare patients facing cancer.

Finally, and most importantly, the proposed rule will create additional fears and concerns for cancer patients. These patients will now receive two bills (instead of one) for their treatment, rely on a vendor several states away and their 'customer support' experts at some 800 number to help them with assistance programs and the fear that their treatment may be disrupted (due to formularies and inventory issues) or denied due to failure to pay their co-pay.

Sincerely,

Dave Dillahunt, CAE
Executive Director

Submitter : Dr. Frank Senecal, MD **Date:** 04/25/2005

Organization : Northwest Medical Specialties

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

To CMS:

See Attachment in WORD Format

CMS-1325-P-296-Attach-1.DOC

To CMS:

Dear Sir:

I am a medical oncologist in Tacoma, Washington. I have been in private practice for 20 years. Our practice services a very large portion of the South Puget Sound region.

My specific comments regarding the proposed CAP option for physicians focuses on the following:

1. **Availability and Access**: Our patients often require rapid changes in treatment. This is most evident in the area of supportive care. Due to neutropenia associated with therapy, many patients need a rapid response to care that might involve growth factors and antibiotic therapy. Similarly, our patients with excessive nausea require a rapid solution. Our ability to respond at the time these symptoms develop is crucial. I cannot see how the current CAP system will give us the flexibility and availability of agents necessary to support our patients.

2. **Dose Adjustments and Wastage**: Frequently our therapies are adjusted based upon a myriad of symptoms. These symptoms may not become evident until the time of the therapy. Doses of chemotherapy drugs may be held or reduced. Different supportive agents to adequately respond to symptoms may be chosen. Some chemotherapy agents result in toxicities 3 to 4 weeks after administration, just preceding the next therapy.

The ability to adjust, have adequate drugs to treat toxicity, and at the time of scheduled therapy is crucial.

How we are to make adjustments and reconcile those with the supplies (wastage) is completely unclear to me.

3. **Administration**: We presently spend a great deal of effort to document therapy, assure accurate billing and adhere to CMS guidelines. It seems to me the potential for great confusion is real with the CAP system. Reconciling billed charges for the drugs and for administration on the surface may seem easy, but far simpler efforts to coordinate these aspects of billing have resulted in rebilling, long delays in payment and in the current system might be a financial disaster for oncologists.

I do not feel that the CAP proposal is ready for implementation, and cannot imagine that in six months the program will be ready. For such a tremendously important process to be implemented, should we not give additional time and effort to working these very real problems out of the system?

Respectfully,

Frank M. Senecal, MD

Submitter : Tom Richardson **Date:** 04/25/2005

Organization : NAMI Whatcom County (Washington State)

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-297-Attach-1.DOC

NAMI of Whatcom County

Located at: Health Support Center
1212 Indian Street in downtown Bellingham
Mail: PO Box 4124, Bellingham, WA 98227
Phone: (360) 671-4950 *Fax*: (360) 671-4950
E-mail: namiwhatcomcounty@earthlink.net
Website: http://www.healthsupportcenter.org/namiwhatcom

April 25, 2005

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1325-P
PO Box 8010
Baltimore, MD 21244-8010

RE: CMS' Part B Competitive Acquisition Program - Categories of Drugs to be Included

To Whom It May Concern:

I am writing on behalf of the members and families of NAMI (National Alliance for the Mentally Ill) Whatcom County, Washington. We support the proposed rule concerning implementation of the Competitive Acquisition Program and ask that injectable antipsychotic medications be included in the initial phase of CAP implementation.

My own son and many others with schizophrenia in our community and across the nation currently use Risperdal Stanza, an injectable form of medication to control the symptoms of their disease. Individuals with severe and persistent mental illnesses often have great difficulty maintaining consistent adherence to their prescribed drug regimens. Getting an injection every two weeks has been something that my son and others have been able to do (with the support of case managers etc.) much more consistently than they've done using alternative daily (or multi-daily) oral medications.

The advantages of injectable psychiatric medications are multifold, but the bottom line is consistent adherence to the treatment regimen and constant blood level maintenance. The injectable medication my son now takes has given him – and those who work to maintain him in community treatment – a critical tool that did not exist until recently. Prior to switching to Risperdal Stanza, my son's life included as much time spent in hospital or jail as in community living.

Patient noncompliance with psychotropic medication regimens is legend – and the cause of untold misery and ineffectiveness in the mental health care system. The President's New Freedom Commission 2003 Report stated, "To achieve the promise of community living for everyone, new service delivery patterns and incentives must ensure that every American has easy and continuous access to the most current treatments and best support services."

In implementing the CAP program, CMS has an opportunity to include injectable psychotropics in the initial phase and thereby make a significant contribution to facilitating patient access to critical psychiatric medications. Noncompliance, frequently resulting in negative outcomes such as rehospitalization, repeated involvement with cops, courts, and incarceration, loss of employment/housing, use of emergency facilities, and suicide, can all be avoided.

The use of injectable antipsychotics has proven to be an important, evidence-based practice that addresses the noncompliance of issue of many with schizophrenia. CMS should make consumer access to injectable antipsychotic medications an urgent priority. And, as other injectable psychotropics become available, CMS should prioritize efforts to ensure expanded consumer access to these drugs.

Community Mental Health Centers (CMHCs) and other community providers serve the largest number of people with severe mental illnesses. Most such "consumers" are eligible for both Medicaid and Medicare. Unless included in phase one of CAP, CMHCs will face serious obstacles in providing injectable medications to mentally ill patients.

CMHCs are generally underfunded non-profit organizations lacking in sophisticated information technology and administrative staffing. Unless injectable psychotropic medications are included in the Part B Competitive Acquisition Program, CMHCs will have to first purchase the medications (with unused financial assets most don't have) and then seek reimbursement from both Medicare (which makes only partial payment for mental health drugs) and Medicaid. They would then bear the administrative burden of tracking the claims and would suffer the financial risk of receiving incomplete payment from one or both payers. Many clinics simply won't (can't) do all that.

Such burdens will become an impediment to expanding access to these medications for the very psychiatric patients who could benefit most from it. In some cases, CMHCs will only provide the medication to patients that are solely Medicaid beneficiaries.

However, if injectable antipsychotics are included in the Medicare CAP program, the substantial impediments will be removed; providers will have the option to obtain the medications from a drug vendor which will shoulder the process of gaining reimbursement from Medicare. Helping providers expand access to these medications will bring great benefit to people with schizophrenia.

It appears that CMS is considering including only oncology medications in the initial phase of the Part B Competitive Acquisition Program. We urge you to include the new injectable psychiatric therapies in the initial program as well.

People with serious mental illnesses are certainly among the most vulnerable people in our society; their brains don't work well when they are untreated. Injectable medications help with consistent treatment thereby saving money and lives. We urge you to include coverage of injectable antipsychotic medications in the drug categories that compose the initial phase of CAP implementation.

Sincerely,

Tom Richardson, Public Policy Chair
NAMI Whatcom County

cc: Larry Richardson, President, NAMI Whatcom County
Dr. Mark McClellan, Administrator
CMS, Rm 445-G
Hubert H. Humphrey Bldg.
200 Independence Avenue, S.W.
Washington, D.C. 20201

Submitter : **Ms. Anne Marie Bicha** **Date: 04/25/2005**

Organization : **American Gastroenterological Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment for comments on specific issues. Thank you.

CMS-1325-P-298-Attach-1.DOC

AMERICAN GASTROENTEROLOGICAL ASSOCIATION

4930 Del Ray Avenue • Bethesda, Maryland 20814-2513
301-654-2055 • Fax 301-654-5920 • member@gastro.org

NATIONAL OFFICE
Executive Vice President
Robert B. Greenberg

PRESIDENT
Emmet B. Keeffe, MD
Stanford University Medical Center
750 Welch Road
Palo Alto, CA 94304-1509
650-498-5691
Fax: 650-498-5692
ekeeffe@stanford.edu

PRESIDENT-ELECT
David A. Peura, MD
434-924-0316
Fax: 434-924-0491
dap8v@virginia.edu

VICE PRESIDENT
Mark Donowitz, MD
410-955-9675
Fax: 410-955-9677
mdonowit@jhmi.edu

SECRETARY/TREASURER
Ian L. Taylor, MD, PhD
504-584-1783
FAX: 504-584-2945
ian.taylor@tulane.edu

PAST PRESIDENT
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www.gastro.org

AGA WEB PORTAL
www.agaportal.org

April 25, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: 2005 Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Proposed Rule

Dear Doctor McClellan:

The American Gastroenterological Association (AGA) is the nation's oldest not-for-profit medical specialty society, and the largest society of gastroenterologists, representing more than 14,000 physicians and scientists who are involved in research, clinical practice, and education on disorders of the digestive system.

The AGA appreciates the opportunity to comment on Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Proposed Rule. We are pleased that the Medicare Prescription Drug, Improvement and Modernization Act of 2003 has enacted legislation allowing for physician choice in how they obtain drugs administered in their offices, whether through the competitive acquisition process (CAP) or through direct purchase with vendors under the average sales price methodology (ASP).

Regardless of how CMS chooses to implement this rule, there will likely be issues and challenges that were not fully considered as part of the proposed rule. We therefore recommend that the final regulations be published as an interim final rule subject to additional notice and comment.

We have identified a number of issues as specified in the categories that follow that need to be resolved prior to the implementation of the CAP program. The goal is to make the CAP program as effective as possible and workable prior to implementation for all parties: physicians, vendors and CMS.

Overview of the CAP

CMS is seeking comments on whether to phase in competitive acquisition bidding by high-volume specialty, by lower volume specialty, or to completely phase in all specialties on the same date. The AGA supports CMS phasing in this rule initially by high-volume specialty (i.e. oncology/hematology). This will enable CMS to work out any potential issues prior to adoption for all specialties.

Categories of Drugs to be Included Under the CAP

The rule provides an example of the most prevalent drugs administered by oncologists. One agent that is infused by gastroenterologists, infliximab (Remicade), is on this list. While oncologists provide over 60% of infliximab for Medicare beneficiaries infused in the physician office, gastroenterologists administer infliximab for Medicare beneficiaries with Crohn's disease.

The proposed rule was unclear on the following issue: If the rule is phased in by specialty, will another specialty who provides a drug on another society's "specialty-specific" list (i.e. oncology) be able to purchase the drug through the CAP as of January 1, 2006? AGA recommends that any drug initially included in the CAP not be restricted by specialty, purpose, diagnosis or off-label use and that CMS provide this clarification in the final rule.

Depending on how finely drug categories are defined, vendors may not want to provide lower volume drugs under the CAP program. CMS will need to monitor marketplace accessibility of the ability to purchase smaller quantity drugs through the ASP system at a reasonable cost. Since ASP was implemented in 2005, there is not enough data at this time to determine the extent of the access problem.

The rule is unclear on whether physicians are restricted in their ability to purchase drugs from multiple vendors. One might interpret the intent of the proposed rule is that an individual physician, or physician practice, must purchase all categories offered by the vendor. AGA recommends that a physician must be allowed to determine which categories to purchase via the CAP program and retain the ability to purchase other drugs via the ASP system.

Competitive Acquisition Areas

AGA recommends that the CAP be implemented on a national basis. Nationwide implementation is essential in order to enable appropriate access to the drugs around the country depending on the specific specialty and differences in volume. AGA believes it would create significant administrative burden on physicians if CMS were to implement a regional or statewide program, especially for physicians that practice in more than one geographic area, such as Maryland – DC – Virginia, Missouri-Kansas, Illinois-Indiana-Wisconsin, New-Jersey-Pennsylvania and Ohio-Kentucky-Indiana.

Claims Processing Overview

CMS is seeking comments on whether it should consider making a partial payment to the vendor in cases where the drug administration claim is not received by the CMS claims processing system within 28 calendar days of the anticipated date of administration. AGA acknowledges that vendors are not paid in full until the drug is administered to the patient. We support CMS'

proposal to make partial payments to vendors. At the same time, CMS should monitor this area and institute controls to prevent potentially fraudulent claims.

CMS interprets the law that it cannot reimburse the vendor until the drug in administered to the patient. AGA believes there needs to be some flexibility in this interpretation to account for specific clinical circumstances. Examples would be when the date of the appointment might change or be canceled or there may be a clinical change in the course of treatment that affects the dose, administration or type of drug that was previously ordered. AGA recommends that CMS review their flexibility in implementing the law that would allow physicians to obtain, within reason, a larger quantity of a drug that is not necessary tied upfront to a specific administration date. AGA would support monitoring requirements to prevent acquisition of drugs through the CAP program that could be provided to patients otherwise not eligible for part B.

At the same time, AGA also recommends that the data elements required as part of the claims submission be as simplified as possible. The comprehensive information for the patient should only be required once, as part of the initial claim, once treatment is commenced. AGA believes there is a way to correlate the administration of the drug back to the beneficiary's comprehensive information using the NCPDP prescription numbers, the NDC descriptor, and the patient's HIPAA compliant identifier number.

The rule also requires the physician to submit the drug administration claim to their carrier within 14 calendar days that was not a requirement in the law. There is no precedent of a 14-day time frame for any other Medicare services. We believe a 14-day time frame will provide an undue burden on smaller and rural practices. We recommend that CMS change this timeframe to 30 calendar days, with the acknowledgement that practices which currently submit within a 14-day time frame will likely continue to do so. A 30-day time frame would alleviate the burden on those practices that do not have the capability of meeting a 14-day time frame. As the Periodic Interim Payment methodology to hospitals established a 30-day timeframe, there is precedent for this recommendation.

For physicians participating in the CAP program, there may be some modest reduction in the staff costs associated with billing the program for drugs. However, AGA absolutely disagrees with the statement on page 10755 of the proposed rule that the CAP program will not create additional burdens on physicians. Actually, the opposite is true. The net impact will be to add significantly to the administrative costs of providing infusion services to patients in their office setting. The added costs flow from the need to maintain a dual ordering and inventory system, the need to match the physician's and the vendor's bills, formulary limitations, and the potentially burdensome rules dealing with the disposition of unused drugs. We suspect that these added costs and administrative headaches would cause most physicians to decide not to enroll in CAP despite the financial benefit in not having to bill for drugs.

We would urge that CMS consider establishing an administrative service fee to be paid to physicians who enroll in CAP to offset some of these added costs. CMS could establish a G code for this purpose. We would think the costs for these payments could be absorbed by CMS from the savings associated with reduced drug expenditures flowing from the CAP.

Bidding Entity Qualifications

AGA does not agree with CMS' requirement that a vendor have three years experience in furnishing drugs to Medicare. If a vendor is a registered pharmacy under appropriate state law, and have a process for providing the drug in a safe and effective manner, that should be sufficient for CAP purposes. The proposed rule language needs to be clarified to reflect that the vendor should have experience furnishing drugs that are commonly provided to the Medicare population, not that the vendor's experience needs to be specifically with the Medicare program.

CAP Bidding Process-Evaluation and Selection

AGA is concerned that CMS' bidding process methodology implies a vendor must bid under ASP+6 in order to be awarded a contract. CMS needs to ensure appropriate access under the CAP program, and not base their contract award to vendors solely based on lowest bid prices. It is unclear in the rule whether sales to CAP vendors will be included in the computation of ASP or best price. AGA is concerned that low CAP bid prices will be reflected in the current ASP system and lower the reimbursement physicians may obtain by directly negotiating with a vendor, therefore further weakening the ASP program. AGA recommends that the CAP prices and the true ASP prices remain separate.

Contract Requirements

AGA recommends that vendors be required to incorporate new drugs into their categories as they receive FDA approval. We also recommend that the vendors should not be allowed to substitute drugs during the one-year contract period until the renewal of the contract. Vendors should also be required, prior a physician signing a contract, to disclose all of the drugs they will be providing in a category.

Under the CAP program, the vendor is responsible for collecting the beneficiary co-insurance. We are concerned that if a beneficiary stops paying their coinsurance during the course of treatment, the vendor could elect to not continue providing the drug to the physician. This would place liability concerns on both parties. We recommend that CMS state in the final rule that the vendor cannot drop a physician from the CAP or withhold shipping drugs due to the inability of the vendor to collect co-insurance from the Medicare beneficiary. We also recommend that the vendor use due process to correct any potential problems with a physician prior to termination.

AGA also recommends clarification in the final rule on issues related to returning drugs to the vendor. Representative examples would be if the wrong drug is shipped, the drug is damaged in transit, or the patient's clinical status has changed and treatment requires a new drug after it has been shipped out by the vendor. We believe these costs should be reflected in the bid prices between CMS and the vendors so the physician is not responsible for bearing these costs.

In addition, some states prohibit the return of drugs after they have been prescribed. CMS needs to clarify in the final rule that the term "drug order" does not mean "prescription", and that it did not mean to overrule state pharmacy laws.

Additional Comments

CMS uses the word "participating" provider in the rule. We request that CMS clarify in the final rule that it is not required that a physician be a participating provider with Medicare in order to participate in the CAP.

The AGA is also very concerned that the combination of inadequate drug fees and scheduled cuts of 26% in Medicare's physician payment rates will force many physicians to stop providing these drugs in their offices. In addition to ensuring that ASP rates are adequate and the CAP is a realistic option, the AGA believes that the Administration must take an active role in averting across-the-board multi-year cuts in payments for physician services. As a first step, AGA recommends that the Secretary use his administrative authority to remove physician-administered drugs from the sustainable growth rate formula, which determines updates in Medicare physician payments, retroactive to the SGR base year (1996). Calculations from the Centers for Medicare & Medicaid Services (CMS) show that the sustainable growth rate formula (SGR) from its inception would moderate or eliminate the 5% yearly decrease scheduled to begin in 2006.

Thank you for consideration of our comments on the CAP proposed rule. We request that issues identified by AGA, other organized medical associations, vendors, and interested parties be given careful analysis and consideration prior to issuance of any final regulation, and again, we request that the regulation be published as an interim final rule.

If we may provide any additional information on our comments, please contact Anne Marie Bicha, AGA Director of Regulatory Affairs at 301-654-2055, ext. 664 or abicha@gastro.org.

Sincerely,

Emmet B. Keeffe, MD
AGA President

Submitter : Mr. Shekh Ali **Date:** 04/25/2005

Organization : Highline West Seattle Mental Health

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern,

I write to you as the Billing Manager for Highline Mental Health to comment on the proposed Competitive Acquisition Program and the need to have psychiatric Part B medications covered in 2006 as part of the Medicare Modernization Act.

Our CMHC has suffered under the medical benefit for inject-able medications billed under Part B. Whether the issues have involved unclear coding requirements or just the labor involved with properly performing the buy and bill process, we have had a miserable experience with it. There can be no doubt that our problems with the current complicated process have lead to fewer patients receiving the treatment that their doctors have selected as the best for them.

I appreciate your hearing my concerns. To reiterate, I encourage you in the strongest terms possible to include psychiatric inject able mediations under the Competitive Acquisition Program. It is in the best interest of both the consumers and the agencies that serve them.

Submitter : Sarah Taylor **Date:** 04/25/2005

Organization : Oncology Hematology Consultants, PSC

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.